TITLES II AND III OF THE COMPREHENSIVE DRUG ABUSE PREVENTION AND CONTROL ACT OF 1970 (PUBLIC LAW 91–513)

[As Amended Through P.L. 117–328, Enacted December 29, 2022]

[Currency: This publication is a compilation of the text of Public Law 91-513. It was last amended by the public law listed in the As Amended Through note above and below at the bottom of each page of the pdf version and reflects current law through the date of the enactment of the public law listed at https://www.govinfo.gov/app/collection/comps/]

[Note: While this publication does not represent an official version of any Federal statute, substantial efforts have been made to ensure the accuracy of its contents. The official version of Federal law is found in the United States Statutes at Large and in the United States Code. The legal effect to be given to the Statutes at Large and the United States Code is established by statute (1 U.S.C. 112, 204).]

TABLE OF CONTENTS

[1] Section 103 was repealed by section 1(b) of Public Law 95–137 without a corresponding amendment to the table of contents.
[2] See footnote to part C set out below.
[3] Sections 310 and 405 were added to the table of contents without being preceded by "Sec.", but reflect the probable intent of Congress.

[4] So in law. Probably should be "Penalty for simple possession." See the heading for section 404 set out below.
[5] Sections 417, 418, 419, 420, 421, 517, 518, and 519 were added to the table of contents without being preceded by "Sec.", but reflect the probable intent of Congress.
[6] So in law. Probably should be "Employment or use of persons under 18 years of age in drug operations." See the heading for section 420 set out below.

[7] See footnote to item number 417.

Section 2(c)(3) of Public Law 106–185 (114 Stat. 21) repealed section 518, but did not make a conforming amendment to the table of contents.

[8] See footnote to item number 417.

So in law. Probably should be "Controlled substances production control.". See the heading for section 519 set out below.

[9] Section 122 of the USA PATRIOT Improvement and Reauthorization Act of 2005 (P.L. 109–177; 120 Stat. 225) provides for an amendment to insert a new section 1010A in part A of the Controlled Substance Import and Export Act (21 U.S.C. 951 et seq.) without providing for a corresponding amendment to the table of sections. The table of contents appears at the beginning of the Comprehensive Drug Abuse Prevention and Control Act of 1970.

TITLE II—CONTROL AND ENFORCEMENT [10]

PART A—SHORT TITLE; FINDINGS AND DECLARATION; DEFINITIONS

SHORT TITLE

SEC. 100. [21 U.S.C. 801 note] This title may be cited as the "Controlled Substances Act".

FINDINGS AND DECLARATIONS

SEC. 101. [21 U.S.C. 801] 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.

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[10] Section 4 of the Comprehensive Drug Abuse Prevention and Control Act of 1970 (42 U.S.C. 290bb–2a) provides as follows: "The Secretary of Health, Education, and Welfare, after consultation with the Attorney General and with national organizations representative of persons with knowledge and experience in the treatment of narcotic addicts, shall determine the appropriate methods of professional practice in the medical treatment of the narcotic addiction of various classes of narcotic addicts, and shall report thereon from time to time to the Congress.".

Section 602 of Public Law 89–793 (42 U.S.C. 3402) provides as follows: "The Surgeon General and the Attorney General are authorized to give representatives of States and local subdivisions thereof the benefit of their experience in the care, treatment, and rehabilitation of narcotic addicts so that each State may be encouraged to provide adequate facilities and personnel for the care and treatment of narcotic addicts in its jurisdiction.". Reorganization Plan No. 3 of 1966 transferred all statutory powers and functions of the Surgeon General, and other officers of the Public Health Service, to the Secretary of Health, Education, and Welfare.

Section 509(b) of the Department of Education Organization Act (20 U.S.C. 3508(b)) provides that references to the Secretary of Health, Education, and Welfare shall be deemed to refer to the Secretary of Health and Human Services.

(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.

DEFINITIONS

SEC. 102. [21 U.S.C. 802] 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. 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.

(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 barbituric acid or any of the salts of barbituric acid; 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.

(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). As used in schedule I(c), the term "isomer" means any optical, positional, or geometric isomer. As used in schedule II(a)(4), 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)(A) Subject to subparagraph (B), the terms "marihuana" and "marijuana" mean 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.

(B) The terms "marihuana" and "marijuana" do not include—

(i) hemp, as defined in section 297A of the Agricultural Marketing Act of 1946; or

(ii) 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, 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"or "opioid" 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 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, or organ, or mental faculty.

(26)[11] The term "State" means a State of the United States, the District of Columbia, and any commonwealth, territory, or possession of the United States.

(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 (C), 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.

[11] Indentation so in law. See section 607(j)(1) of Public Law 104–294.

(B) The designation of gamma butyrolactone or any other chemical as a listed chemical pursuant to paragraph (34) or (35) does not preclude a finding pursuant to subparagraph (A) of this paragraph that the chemical is a controlled substance analogue.

(C) 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 to 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

(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) Isosafrole. [12]

(Q) Safrole.

(R) Piperonal.

(S) N-Methylephedrine. [13]

(T) N-methylpseudoephedrine.

(U) Hydriodic acid. [13]

[12] Indentation so in law. See section 209 of Public Law 104–237.
[13] Indentation so in law. See section 209 of Public Law 104–237.

(V) Benzaldehyde.
(W) Nitroethane.
(X) Gamma butyrolactone.
(Y) 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.
(F) [14] Potassium permanaganate.
(G) 2-Butanone (or Methyl Ethyl Ketone). [15]
(H) Toluene.
(I) Iodine. [15]
(J) Hydrochloric gas. [15]

(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,

[14] Subparagraph (E) was repealed by section 2301(b) of Public Law 101–647 (104 Stat. 4858).
[15] Indentation so in law. See sections 204(a) and 209 of Public Law 104–237.

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;

(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, subject to clause (v), unless—

(I) the Attorney General has determined under section 204 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 the 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;

(v) any transaction in a scheduled listed chemical product that is a sale at retail by a regulated seller or a distributor required to submit reports under section 310(b)(3); or

(vi) 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, corticosteroids, and dehydroepiandrosterone), and includes—

(i) androstanediol—

(I) 3β,17β-dihydroxy-5α-androstane; and

(II) 3α,17β-dihydroxy-5α-androstane;

(ii) androstanedione (5α-androstan-3,17-dione);

(iii) androstenediol—

(I) 1-androstenediol (3β,17β-dihydroxy-5α-androst-1-ene);

(II) 1-androstenediol (3α,17β-dihydroxy-5α-androst-1-ene);

(III) 4-androstenediol (3β,17β-dihydroxy-androst-4-ene); and
(IV) 5-androstenediol (3β,17β-dihydroxy-androst-5-ene);
(iv) androstenedione—
(I) 1-androstenedione ([5α]-androst-1-en-3,17-dione);
(II) 4-androstenedione (androst-4-en-3,17-dione); and
(III) 5-androstenedione (androst-5-en-3,17-dione);
(v) bolasterone (7α,17α-dimethyl-17β-hydroxyandrost-4-en-3-one);
(vi) boldenone (17β-hydroxyandrost-1,4,-diene-3-one);
(vii) calusterone (7β,17α-dimethyl-17β-hydroxyandrost-4-en-3-one);
(viii) clostebol (4-chloro-17β-hydroxyandrost-4-en-3-one);
(ix) dehydrochloromethyltestosterone (4-chloro-17β-hydroxy-17α-methyl-androst-1,4-dien-3-one);
(x) Δ 1-dihydrotestosterone (a.k.a. "1-testosterone") (17β-hydroxy-5α-androst-1-en-3-one);
(xi) 4-dihydrotestosterone (17β-hydroxy-androstan-3-one);
(xii) drostanolone (17β-hydroxy-2α-methyl-5α-androstan-3-one);
(xiii) ethylestrenol (17α-ethyl-17β-hydroxyestr-4-ene);
(xiv) fluoxymesterone (9-fluoro-17α-methyl-11β,17β-dihydroxyandrost-4-en-3-one);
(xv) formebolone (2-formyl-17α-methyl-11α,17β-dihydroxyandrost-1,4-dien-3-one);
(xvi) furazabol (17α-methyl-17β-hydroxyandrostano[2,3-c]-furazan);
(xvii) 13β-ethyl-17β-hydroxygon-4-en-3-one;
(xviii) 4-hydroxytestosterone (4,17β-dihydroxy-androst-4-en-3-one);
(xix) 4-hydroxy-19-nortestosterone (4,17β-dihydroxy-estr-4-en-3-one);
(xx) mestanolone (17α-methyl-17β-hydroxy-5α-androstan-3-one);
(xxi) mesterolone (1α-methyl-17β-hydroxy-[5α]-androstan-3-one);
(xxii) methandienone (17α-methyl-17β-hydroxyandrost-1,4-dien-3-one);
(xxiii) methandriol (17α-methyl-3β,17β-dihydroxyandrost-5-ene);
(xxiv) methenolone (1-methyl-17β-hydroxy-5α-androst-1-en-3-one);
(xxv) 17α-methyl-3β, 17β-dihydroxy-5α-androstane;
(xxvi) 17α-methyl-3α,17β-dihydroxy-5α-androstane;
(xxvii) 17α-methyl-3β,17β-dihydroxyandrost-4-ene.
(xxviii) 17α-methyl-4-hydroxynandrolone (17α-methyl-4-hydroxy-17β-hydroxyestr-4-en-3-one);
(xxix) methyldienolone (17α-methyl-17β-hydroxyestra-4,9(10)-dien-3-one);
(xxx) methyltrienolone (17α-methyl-17β-hydroxyestra-4,9-11-trien-3-one);
(xxxi) methyltestosterone (17α-methyl-17β-hydroxyandrost-4-en-3-one);

(xxxii) mibolerone (7α,17α-dimethyl-17β-hydroxyestr-4-en-3-one);
(xxxiii) 17α-methyl-Δ1-dihydrotestosterone (17β-hydroxy-17α-methyl-5α-androst-1-en-3-one) (a.k.a. "17-α-methyl-1-testosterone");
(xxxiv) nandrolone (17β-hydroxyestr-4-en-3-one);
(xxxv) norandrostenediol—
(I) 19-nor-4-androstenediol (3β, 17β-dihydroxyestr-4-ene);
(II) 19-nor-4-androstenediol (3α, 17β-dihydroxyestr-4-ene);
(III) 19-nor-5-androstenediol (3β, 17β-dihydroxyestr-5-ene); and
(IV) 19-nor-5-androstenediol (3α, 17β-dihydroxyestr-5-ene);
(xxxvi) norandrostenedione—
(I) 19-nor-4-androstenedione (estr-4-en-3,17-dione); and
(II) 19-nor-5-androstenedione (estr-5-en-3,17-dione;
(xxxvii) norbolethone (13β,17α-diethyl-17β-hydroxygon-4-en-3-one);
(xxxviii) norclostebol (4-chloro-17β-hydroxyestr-4-en-3-one);
(xxxix) norethandrolone (17α-ethyl-17β-hydroxyestr-4-en-3-one);
(xl) normethandrolone (17α-methyl-17β-hydroxyestr-4-en-3-one);
(xli) oxandrolone (17α-methyl-17β-hydroxy-2-oxa-[5α]-androstan-3-one);
(xlii) oxymesterone (17α-methyl-4,17β-dihydroxyandrost-4-en-3-one);
(xliii) oxymetholone (17α-methyl-2-hydroxymethylene-17β-hydroxy-[5α]-androstan-3-one);
(xliv) stanozolol (17α-methyl-17β-hydroxy-[5α]-androst-2-eno[3,2-c]-pyrazole);
(xlv) stenbolone (17β-hydroxy-2-methyl-[5α]-androst-1-en-3-one);
(xlvi) testolactone (13-hydroxy-3-oxo-13,17-secoandrosta-1,4-dien-17-oic acid lactone);
(xlvii) testosterone (17β-hydroxyandrost-4-en-3-one);
(xlviii) tetrahydrogestrinone (13β,17α-diethyl-17β-hydroxygon-4,9,11-trien-3-one);
(xlix) trenbolone (17β-hydroxyestr-4,9,11-trien-3-one);
(l) 5α-Androstan-3,6,17-trione;
(li) 6-bromo-androstan-3,17-dione;
(lii) 6-bromo-androsta-1,4-diene-3,17-dione;
(liii) 4-chloro-17α-methyl-androsta-1,4-diene-3,17β-diol;
(liv) 4-chloro-17α-methyl-androst-4-ene-3β,17β-diol;
(lv) 4-chloro-17α-methyl-17β-hydroxy-androst-4-en-3-one;
(lvi) 4-chloro-17α-methyl-17β-hydroxy-androst-4-ene-3,11-dione;
(lvii) 4-chloro-17α-methyl-androsta-1,4-diene-3,17β-diol;
(lviii) 2α,17α-dimethyl-17β-hydroxy-5α-androstan-3-one;
(lix) 2α,17α-dimethyl-17β-hydroxy-5β-androstan-3-one;
(lx) 2α,3α-epithio-17α-methyl-5α-androstan-17β-ol;

(lxi) [3,2-c]-furazan-5α-androstan-17β-ol;
(lxii) 3β-hydroxy-estra-4,9,11-trien-17-one;
(lxiii) 17α-methyl-androst-2-ene-3,17β-diol;
(lxiv) 17α-methyl-androsta-1,4-diene-3,17β-diol;
(lxv) Estra-4,9,11-triene-3,17-dione;
(lxvi) 18a-Homo-3-hydroxy-estra-2,5(10)-dien-17-one;
(lxvii) 6α-Methyl-androst-4-ene-3,17-dione;
(lxviii) 17α-Methyl-androstan-3-hydroxyimine-17β-ol;
(lxix) 17α-Methyl-5α-androstan-17β-ol;
(lxx) 17β-Hydroxy-androstano[2,3-d]isoxazole;
(lxxi) 17β-Hydroxy-androstano[3,2-c]isoxazole;
(lxxii) 4-Hydroxy-androst-4-ene-3,17-dione[3,2-c]pyrazole-5α-androstan-17β-ol;
(lxxiii) [3,2-c]pyrazole-androst-4-en-17β-ol;
(lxxiv) [3,2-c]pyrazole-5α-androstan-17β-ol; and
(lxxv) any salt, ester, or ether of a drug or substance described in this paragraph.

The substances excluded under this subparagraph may at any time be scheduled by the Attorney General in accordance with the authority and requirements of subsections (a) through (c) of section 201.

(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).

(C)(i) Subject to clause (ii), a drug or hormonal substance (other than estrogens, progestins, corticosteroids, and dehydroepiandrosterone) that is not listed in subparagraph (A) and is derived from, or has a chemical structure substantially similar to, 1 or more anabolic steroids listed in subparagraph (A) shall be considered to be an anabolic steroid for purposes of this Act if—

(I) the drug or substance has been created or manufactured with the intent of producing a drug or other substance that either—

(aa) promotes muscle growth; or

(bb) otherwise causes a pharmacological effect similar to that of testosterone; or

(II) the drug or substance has been, or is intended to be, marketed or otherwise promoted in any manner suggesting that consuming it will promote muscle growth or any other pharmacological effect similar to that of testosterone.

(ii) A substance shall not be considered to be a drug or hormonal substance for purposes of this subparagraph if it—

(I) is—

(aa) an herb or other botanical;

(bb) a concentrate, metabolite, or extract of, or a constituent isolated directly from, an herb or other botanical; or

(cc) a combination of 2 or more substances described in item (aa) or (bb);

(II) is a dietary ingredient for purposes of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.); and

(III) is not anabolic or androgenic.

(iii) In accordance with section 515(a), any person claiming the benefit of an exemption or exception under clause (ii) shall bear the burden of going forward with the evidence with respect to such exemption or exception.

(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) [16] 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, anabolic steroids, or depressant or stimulant substances.

(45)(A) The term "scheduled listed chemical product" means, subject to subparagraph (B), a product that—

(i) contains ephedrine, pseudoephedrine, or phenylpropanolamine; and

(ii) may be marketed or distributed lawfully in the United States under the Federal, Food, Drug, and Cosmetic Act as a nonprescription drug.

Each reference in clause (i) to ephedrine, pseudoephedrine, or phenylpropanolamine includes each of the salts, optical isomers, and salts of optical isomers of such chemical.

(B) Such term does not include a product described in subparagraph (A) if the product contains a chemical specified in such subparagraph that the Attorney General has under section 201(a) added to any of the schedules under section 202(c). In the absence of such scheduling by the Attorney General, a chemical specified in such subparagraph may not be considered to be a controlled substance.

(46) The term "regulated seller" means a retail distributor (including a pharmacy or a mobile retail vendor), except that such term does not include an employee or agent of such distributor.

(47) The term "mobile retail vendor" means a person or entity that makes sales at retail from a stand that is intended to be temporary, or is capable of being moved from one location to another, whether the stand is located within or on the premises of a fixed facility (such as a kiosk at a shopping center or an airport) or

[16] Paragraph (44) as shown above reflects the amendment made by subsection (a)(2) of section 2 of Public Law 108–358 (118 Stat. 1663). Subsection (d) of such section provides that "the amendments made by this section shall take effect 90 days after the date of enactment of this Act". Such Public Law was enacted October 22, 2004.

whether the stand is located on unimproved real estate (such as a lot or field leased for retail purposes).

(48) The term "at retail", with respect to the sale or purchase of a scheduled listed chemical product, means a sale or purchase for personal use, respectively.

(49)(A)[17] The term "retail distributor" means a grocery store, general merchandise store, drug store, or other entity or person whose activities as a distributor relating to ephedrine, pseudoephedrine, or phenylpropanolamine products are limited almost exclusively to sales for personal use, both in number of sales and volume of sales, either directly to walk-in customers or in face-to-face transactions by direct sales.

(B) For purposes of this paragraph, entities are defined by reference to the Standard Industrial Classification (SIC) code, as follows:

(i) A grocery store is an entity within SIC code 5411.

(ii) A general merchandise store is an entity within SIC codes 5300 through 5399 and 5499.

(iii) A drug store is an entity within SIC code 5912.

(50) The term "Internet" means collectively the myriad of computer and telecommunications facilities, including equipment and operating software, which comprise the interconnected worldwide network of networks that employ the Transmission Control Protocol/Internet Protocol, or any predecessor or successor protocol to such protocol, to communicate information of all kinds by wire or radio.

(51) The term "deliver, distribute, or dispense by means of the Internet" refers, respectively, to any delivery, distribution, or dispensing of a controlled substance that is caused or facilitated by means of the Internet.

(52) The term "online pharmacy"—

(A) means a person, entity, or Internet site, whether in the United States or abroad, that knowingly or intentionally delivers, distributes, or dispenses, or offers or attempts to deliver, distribute, or dispense, a controlled substance by means of the Internet; and

(B) does not include—

(i) manufacturers or distributors registered under subsection (a), (b), (e), or (f) of section 303 who do not dispense controlled substances to an unregistered individual or entity;

(ii) nonpharmacy practitioners who are registered under section 303(g) and whose activities are authorized by that registration;

(iii) any hospital or other medical facility that is operated by an agency of the United States (including the Armed Forces), provided such hospital or other facility is registered under section 303(g);

(iv) a health care facility owned or operated by an Indian tribe or tribal organization, only to the extent such facility is carrying out a contract or compact under the Indian Self-Determination and Education Assistance Act;

[17] Indentation so in law. See section 401(b)(4) of Public Law 104–237.

(v) any agent or employee of any hospital or facility referred to in clause (iii) or (iv), provided such agent or employee is lawfully acting in the usual course of business or employment, and within the scope of the official duties of such agent or employee, with such hospital or facility, and, with respect to agents or employees of health care facilities specified in clause (iv), only to the extent such individuals are furnishing services pursuant to the contracts or compacts described in such clause;

(vi) mere advertisements that do not attempt to facilitate an actual transaction involving a controlled substance;

(vii) a person, entity, or Internet site that is not in the United States and does not facilitate the delivery, distribution, or dispensing of a controlled substance by means of the Internet to any person in the United States;

(viii) a pharmacy registered under section 303(g) whose dispensing of controlled substances via the Internet consists solely of—

(I) refilling prescriptions for controlled substances in schedule III, IV, or V, as defined in paragraph (55); or

(II) filling new prescriptions for controlled substances in schedule III, IV, or V, as defined in paragraph (56); or

(ix) any other persons for whom the Attorney General and the Secretary have jointly, by regulation, found it to be consistent with effective controls against diversion and otherwise consistent with the public health and safety to exempt from the definition of an "online pharmacy".

(53) The term "homepage" means the opening or main page or screen of the website of an online pharmacy that is viewable on the Internet.

(54) The term "practice of telemedicine" means, for purposes of this title, the practice of medicine in accordance with applicable Federal and State laws by a practitioner (other than a pharmacist) who is at a location remote from the patient and is communicating with the patient, or health care professional who is treating the patient, using a telecommunications system referred to in section 1834(m) of the Social Security Act, which practice—

(A) is being conducted—

(i) while the patient is being treated by, and physically located in, a hospital or clinic registered under section 303(g); and

(ii) by a practitioner—

(I) acting in the usual course of professional practice;

(II) acting in accordance with applicable State law; and

(III) registered under section 303(g) in the State in which the patient is located, unless the practitioner—

(aa) is exempted from such registration in all States under section 302(d); or

(bb) is—

(AA) an employee or contractor of the Department of Veterans Affairs who is acting in the scope of such employment or contract; and

(BB) registered under section 303(g) in any State or is utilizing the registration of a hospital or clinic operated by the Department of Veterans Affairs registered under section 303(g);

(B) is being conducted while the patient is being treated by, and in the physical presence of, a practitioner—

(i) acting in the usual course of professional practice;

(ii) acting in accordance with applicable State law; and

(iii) registered under section 303(g) in the State in which the patient is located, unless the practitioner—

(I) is exempted from such registration in all States under section 302(d); or

(II) is—

(aa) an employee or contractor of the Department of Veterans Affairs who is acting in the scope of such employment or contract; and

(bb) registered under section 303(g) in any State or is using the registration of a hospital or clinic operated by the Department of Veterans Affairs registered under section 303(g);

(C) is being conducted by a practitioner—

(i) who is an employee or contractor of the Indian Health Service, or is working for an Indian tribe or tribal organization under its contract or compact with the Indian Health Service under the Indian Self-Determination and Education Assistance Act;

(ii) acting within the scope of the employment, contract, or compact described in clause (i); and

(iii) who is designated as an Internet Eligible Controlled Substances Provider by the Secretary under section 311(g)(2);

(D)(i) is being conducted during a public health emergency declared by the Secretary under section 319 of the Public Health Service Act; and

(ii) involves patients located in such areas, and such controlled substances, as the Secretary, with the concurrence of the Attorney General, designates, provided that such designation shall not be subject to the procedures prescribed by subchapter II of chapter 5 of title 5, United States Code;

(E) is being conducted by a practitioner who has obtained from the Attorney General a special registration under section 311(h);

(F) is being conducted—

(i) in a medical emergency situation—

(I) that prevents the patient from being in the physical presence of a practitioner registered under section 303(g) who is an employee or contractor of the Veterans Health Administration acting in the usual course of business and employment and within the

scope of the official duties or contract of that employee or contractor;

(II) that prevents the patient from being physically present at a hospital or clinic operated by the Department of Veterans Affairs registered under section 303(g);

(III) during which the primary care practitioner of the patient or a practitioner otherwise practicing telemedicine within the meaning of this paragraph is unable to provide care or consultation; and

(IV) that requires immediate intervention by a health care practitioner using controlled substances to prevent what the practitioner reasonably believes in good faith will be imminent and serious clinical consequences, such as further injury or death; and

(ii) by a practitioner that—

(I) is an employee or contractor of the Veterans Health Administration acting within the scope of that employment or contract;

(II) is registered under section 303(g) in any State or is utilizing the registration of a hospital or clinic operated by the Department of Veterans Affairs registered under section 303(g); and

(III) issues a controlled substance prescription in this emergency context that is limited to a maximum of a 5-day supply which may not be extended or refilled; or

(G) is being conducted under any other circumstances that the Attorney General and the Secretary have jointly, by regulation, determined to be consistent with effective controls against diversion and otherwise consistent with the public health and safety.

(55) The term "refilling prescriptions for controlled substances in schedule III, IV, or V"—

(A) means the dispensing of a controlled substance in schedule III, IV, or V in accordance with refill instructions issued by a practitioner as part of a valid prescription that meets the requirements of subsections (b) and (c) of section 309, as appropriate; and

(B) does not include the issuance of a new prescription to an individual for a controlled substance that individual was previously prescribed.

(56) The term "filling new prescriptions for controlled substances in schedule III, IV, or V" means filling a prescription for an individual for a controlled substance in schedule III, IV, or V, if—

(A) the pharmacy dispensing that prescription has previously dispensed to the patient a controlled substance other than by means of the Internet and pursuant to the valid prescription of a practitioner that meets the applicable requirements of subsections (b) and (c) of section 309 (in this paragraph referred to as the "original prescription");

(B) the pharmacy contacts the practitioner who issued the original prescription at the request of that individual to deter-

mine whether the practitioner will authorize the issuance of a new prescription for that individual for the controlled substance described in subparagraph (A); and

(C) the practitioner, acting in the usual course of professional practice, determines there is a legitimate medical purpose for the issuance of the new prescription.

(57)[18] The term "suspicious order" may include, but is not limited to—

(A) an order of a controlled substance of unusual size;

(B) an order of a controlled substance deviating substantially from a normal pattern; and

(C) orders of controlled substances of unusual frequency.

(57)[19] The term "serious drug felony" means an offense described in section 924(e)(2) of title 18, United States Code, for which—

(A) the offender served a term of imprisonment of more than 12 months; and

(B) the offender's release from any term of imprisonment was within 15 years of the commencement of the instant offense.

(58) The term "serious violent felony" means—

(A) an offense described in section 3559(c)(2) of title 18, United States Code, for which the offender served a term of imprisonment of more than 12 months; and

(B) any offense that would be a felony violation of section 113 of title 18, United States Code, if the offense were committed in the special maritime and territorial jurisdiction of the United States, for which the offender served a term of imprisonment of more than 12 months.

PART B—AUTHORITY TO CONTROL; STANDARDS AND SCHEDULES

AUTHORITY AND CRITERIA FOR CLASSIFICATION OF SUBSTANCES

SEC. 201. [21 U.S.C. 811] (a) 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 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 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.

[18] Margin so in law.
[19] There are two paragraph (57)s'.

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. 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) 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) In making any finding under subsection (a) of this section or under subsection (b) of section 202, 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)(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) and with-

out regard to the procedures prescribed by subsections (a) and (b) of this section.

(2)[20] (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 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 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 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 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)[21] When the United States receives notification of a scheduling decision pursuant to article 2 of the Convention on 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 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, 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

[20] Paragraphs (2) through (5) 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. See section 112 of Public Law 95–633. The Convention entered into force in respect to the United States on July 15, 1980.

[21] See footnote for paragraph (2).

Act, 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 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 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 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)[22] If the Attorney General determines, after consultation with the Secretary of Health, Education, and Welfare, that proceedings initiated under recommendations made under paragraph[23] (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

[22] See footnote for paragraph (2).
[23] So in law. Probably should be "subparagraph".

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 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 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 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) 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 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) The Attorney General may, without regard to the findings required by subsection (a) of this section or section 202(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) 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)(1) The Attorney General shall by regulation exclude any nonnarcotic drug which contains a controlled substance from the application of titles II and III of the Comprehensive Drug Abuse Prevention and Control Act (21 U.S.C. 802 et seq.)[24] if such drug may, under the Federal Food, Drug, and Cosmetic Act, be lawfully sold over the counter without a prescription.

(2) Dextromethorphan shall not be deemed to be included in any schedule by reason of enactment of this title unless controlled after the date of such enactment 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

[24] So in law. See section 2(b)(1) of Public Law 108–358 (118 Stat. 1663). Probably should be "this title and title III of this Act". Section 201 above is part of title II of the Comprehensive Drug Abuse Prevention and Control Act of 1970 (21 U.S.C. 201 et seq.). That Act contains a title III, which relates to imports and exports of controlled substances. (Title II of the Act has a separate short title, the "Controlled Substances Act". Title III of the Act also has a separate short title, the "Controlled Substances Import and Export Act".)

are included there 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.

(C) Upon the recommendation of the Secretary of Health and Human Services, a compound, mixture, or preparation which contains any anabolic steroid, which is intended for administration to a human being or an animal, and which, because of its concentration, preparation, formulation or delivery system, does not present any significant potential for abuse.

(h)(1) If the Attorney General finds that the scheduling of a substance in schedule I on a temporary basis is necessary to avoid an imminent hazard to the public safety, he may, by order and without regard to the requirements of subsection (b) relating to the Secretary of Health and Human Services, schedule such substance in schedule I if the substance is not listed in any other schedule in section 202 or if no exemption or approval is in effect for the substance under section 505 of the Federal Food, Drug, and Cosmetic Act. 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 2 years 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 1 year.

(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.

(i) TEMPORARY AND PERMANENT SCHEDULING OF RECENTLY EMERGED ANABOLIC STEROIDS.—

(1) The Attorney General may issue a temporary order adding a drug or other substance to the definition of anabolic steroids if the Attorney General finds that—

(A) the drug or other substance satisfies the criteria for being considered an anabolic steroid under section 102(41) but is not listed in that section or by regulation of the Attorney General as being an anabolic steroid; and

(B) adding such drug or other substance to the definition of anabolic steroids will assist in preventing abuse or misuse of the drug or other substance.

(2) An order issued under paragraph (1) shall not take effect until 30 days after 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. The order shall expire not later than 24 months after the date it becomes effective, except that the Attorney General may, during the pendency of proceedings under paragraph (6), extend the temporary scheduling order for up to 6 months.

(3) 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.

(4) A temporary scheduling order issued under paragraph (1) shall be vacated upon the issuance of a permanent scheduling order under paragraph (6).

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

(6) The Attorney General may, by rule, issue a permanent order adding a drug or other substance to the definition of anabolic steroids if such drug or other substance satisfies the criteria for being considered an anabolic steroid under section 102(41). Such rulemaking may be commenced simultaneously with the issuance of the temporary order issued under paragraph (1).

(j)(1) With respect to a drug referred to in subsection (f), if the Secretary of Health and Human Services recommends that the Attorney General control the drug in schedule II, III, IV, or V pursuant to subsections (a) and (b), the Attorney General shall, not later than 90 days after the date described in paragraph (2), issue an interim final rule controlling the drug in accordance with such subsections and section 202(b) using the procedures described in paragraph (3).

(2) The date described in this paragraph shall be the later of—

(A) the date on which the Attorney General receives the scientific and medical evaluation and the scheduling recommendation from the Secretary of Health and Human Services in accordance with subsection (b); or

(B) the date on which the Attorney General receives notification from the Secretary of Health and Human Services that

the Secretary has approved an application under section 505(c), 512, or 571 of the Federal Food, Drug, and Cosmetic Act or section 351(a) of the Public Health Service Act, or indexed a drug under section 572 of the Federal Food, Drug, and Cosmetic Act, with respect to the drug described in paragraph (1).

(3) A rule issued by the Attorney General under paragraph (1) shall become immediately effective as an interim final rule without requiring the Attorney General to demonstrate good cause therefor. The interim final rule shall give interested persons the opportunity to comment and to request a hearing. After the conclusion of such proceedings, the Attorney General shall issue a final rule in accordance with the scheduling criteria of subsections (b), (c), and (d) of this section and section 202(b).

SCHEDULES OF CONTROLLED SUBSTANCES

SEC. 202. [21 U.S.C. 812] (a) 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 and shall be updated and republished on an annual basis thereafter.

(b) 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)[25] Schedules I, II, III, IV, and V shall, unless and until amended pursuant to section 201, 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) Alphacetylmathadol.[26]
(4) Alphameprodine.
(5) Alphamethadol.
(6) Benzethidine.
(7) Betacetylmethadol.
(8) Betameprodine.
(9) Betamethadol.
(10) Betaprodine.
(11) Clonitazene.
(12) Dextromoramide.
(13) Dextrorphan.
(14) Diampromide.
(15) Diethylthiambutene.
(16) Dimenoxadol.
(17) Dimepheptanol.

[25] For current placement of substances in the schedules, see part 1308 of title 21, Code of Federal Regulations. Note that the schedules as they appear in section 202 may not show all controlled substances, and in some cases a substance may actually be on a different schedule than shown in section 202. This is because the Attorney General has rulemaking authority under section 201(a) to add substances to the schedules, to transfer substances from one schedule to another, and to remove substances from the schedules.

[26] So in law. Probably should be "Alphacetylmethadol."

(18) Dimethylthiambutene.
(19) Dioxaphetyl butyrate.
(20) Dipipanone.
(21) Ethylmethylthiambutene.
(22) Etonitazene.
(23) Etoxeridine.
(24) Furethidine.
(25) Hydroxypethidine.
(26) Ketobemidone.
(27) Levomoramide.
(28) Levophenacylmorphan.
(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) Hydromorphinol.
(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-dimethoxy amphetamine.
(8) Ibogaine.
(9) Lysergic acid diethylamide.
(10) Marihuana.
(11) Mescaline.
(12) Peyote.
(13) N-ethyl-3-piperidyl benzilate.
(14) N-methyl-3-piperidyl benzilate.
(15) Psilocybin.
(16) Psilocyn.
(17) Tetrahydrocannabinols, except for tetrahydrocannabinols in hemp (as defined under section 297A of the Agricultural Marketing Act of 1946).
(18) 4-methylmethcathinone (Mephedrone).
(19) 3,4-methylenedioxypyrovalerone (MDPV).
(20) 2-(2,5-Dimethoxy-4-ethylphenyl)ethanamine (2C–E).
(21) 2-(2,5-Dimethoxy-4-methylphenyl)ethanamine (2C–D).
(22) 2-(4-Chloro-2,5-dimethoxyphenyl)ethanamine (2C–C).
(23) 2-(4-Iodo-2,5-dimethoxyphenyl)ethanamine (2C–I).
(24) 2-[4-(Ethylthio)-2,5-dimethoxyphenyl]ethanamine (2C–T–2).
(25) 2-[4-(Isopropylthio)-2,5-dimethoxyphenyl]ethanamine (2C–T–4).
(26) 2-(2,5-Dimethoxyphenyl)ethanamine (2C–H).
(27) 2-(2,5-Dimethoxy-4-nitro-phenyl)ethanamine (2C–N).
(28) 2-(2,5-Dimethoxy-4-(n)-propylphenyl)ethanamine (2C–P).

(d)(1) Unless specifically exempted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of cannabimimetic agents, or which contains 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.

(2) In paragraph (1):

(A) The term "cannabimimetic agents" means any substance that is a cannabinoid receptor type 1 (CB1 receptor) agonist as demonstrated by binding studies and functional assays within any of the following structural classes:

(i) 2-(3-hydroxycyclohexyl)phenol with substitution at the 5-position of the phenolic ring by alkyl or alkenyl, whether or not substituted on the cyclohexyl ring to any extent.

(ii) 3-(1-naphthoyl)indole or 3-(1-naphthylmethane)indole by substitution at the nitrogen

atom of the indole ring, whether or not further substituted on the indole ring to any extent, whether or not substituted on the naphthoyl or naphthyl ring to any extent.

(iii) 3-(1-naphthoyl)pyrrole by substitution at the nitrogen atom of the pyrrole ring, whether or not further substituted in the pyrrole ring to any extent, whether or not substituted on the naphthoyl ring to any extent.

(iv) 1-(1-naphthylmethylene)indene by substitution of the 3-position of the indene ring, whether or not further substituted in the indene ring to any extent, whether or not substituted on the naphthyl ring to any extent.

(v) 3-phenylacetylindole or 3-benzoylindole by substitution at the nitrogen atom of the indole ring, whether or not further substituted in the indole ring to any extent, whether or not substituted on the phenyl ring to any extent.

(B) Such term includes—

(i) 5-(1,1-dimethylheptyl)-2-[(1R,3S)-3-hydroxycyclohexyl][]-phenol (CP–47,497);

(ii) 5-(1,1-dimethyloctyl)-2-[(1R,3S)-3-hydroxycyclohexyl]-phenol (cannabicyclohexanol or CP–47,497 C8-homolog);

(iii) 1-pentyl-3-(1-naphthoyl)indole (JWH–018 and AM678);

(iv) 1-butyl-3-(1-naphthoyl)indole (JWH–073);

(v) 1-hexyl-3-(1-naphthoyl)indole (JWH–019);

(vi) 1-[2-(4-morpholinyl)ethyl]-3-(1-naphthoyl)indole (JWH–200);

(vii) 1-pentyl-3-(2-methoxyphenylacetyl)indole (JWH–250);

(viii) 1-pentyl-3-[1-(4-methoxynaphthoyl)]indole (JWH–081);

(ix) 1-pentyl-3-(4-methyl-1-naphthoyl)indole (JWH–122);

(x) 1-pentyl-3-(4-chloro-1-naphthoyl)indole (JWH–398);

(xi) 1-(5-fluoropentyl)-3-(1-naphthoyl)indole (AM2201);

(xii) 1-(5-fluoropentyl)-3-(2-iodobenzoyl)indole (AM694);

(xiii) 1-pentyl-3-[(4-methoxy)-benzoyl]indole (SR–19 and RCS–4);

(xiv) 1-cyclohexylethyl-3-(2-methoxyphenylacetyl)indole (SR–18 and RCS–8); and

(xv) 1-pentyl-3-(2-chlorophenylacetyl)indole (JWH–203).

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[27] 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.

[27] So in law. Probably should be "Coca".

SCHEDULE III

(a)[28] 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,

[28] The substances referred to in schedule III(a) have been administratively moved to schedule II.

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.

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.

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.

TREATMENT OF CONTROLLED SUBSTANCE ANALOGUES

SEC. 203. [21 U.S.C. 813] (a) IN GENERAL.—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.

(b) DETERMINATION.—In determining whether a controlled substance analogue was intended for human consumption under sub-

section (a), the following factors may be considered, along with any other relevant factors:

(1) The marketing, advertising, and labeling of the substance.

(2) The known efficacy or usefulness of the substance for the marketed, advertised, or labeled purpose.

(3) The difference between the price at which the substance is sold and the price at which the substance it is purported to be or advertised as is normally sold.

(4) The diversion of the substance from legitimate channels and the clandestine importation, manufacture, or distribution of the substance.

(5) Whether the defendant knew or should have known the substance was intended to be consumed by injection, inhalation, ingestion, or any other immediate means.

(6) Any controlled substance analogue that is manufactured, formulated, sold, distributed, or marketed with the intent to avoid the provisions of existing drug laws.

(c) LIMITATION.—For purposes of this section, evidence that a substance was not marketed, advertised, or labeled for human consumption, by itself, shall not be sufficient to establish that the substance was not intended for human consumption.

REMOVAL OF EXEMPTION OF CERTAIN DRUGS

SEC. 204. [21 U.S.C. 814] (a) REMOVAL OF EXEMPTION.—The Attorney General shall by regulation remove from exemption under section 102(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 par-

ticular 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.

PART C—REGISTRATION OF MANUFACTURERS, DISTRIBUTORS, AND DISPENSERS OF CONTROLLED SUBSTANCES; PIPERIDINE REPORTING [29]

RULES AND REGULATIONS

SEC. 301. [21 U.S.C. 821] The Attorney General is authorized to promulgate rules and regulations and to charge reasonable fees

[29] Prior to the enactment of Public Law 100–690, section 310 of this title concerned reporting requirements regarding the distribution, sale, or import of piperidine. Section 6052 of such Public Law (102 Stat. 4312) amended section 310 in its entirety, with the result that the section now concerns reporting requirements related to listed chemicals, tableting machines, and encapsulating machines. Section 6054 of such Public Law (102 Stat. 4316) made amendments to the definitions in section 102 of this title, including establishing definitions for the terms "listed chemical" and "listed precursor chemical". Piperidine and its salts were included as listed precursor chemicals.

Section 2(a) of Public Law 103–200 (107 Stat. 2333) made amendments to the definitions in section 102 of this title, including replacing the term "listed precursor chemical" with the term

Continued

relating to the registration and control of the manufacture, distribution, and dispensing of controlled substances and to listed chemicals.

PERSONS REQUIRED TO REGISTER

SEC. 302. [21 U.S.C. 822] (a)(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.

(3)(A) Except as provided in subparagraph (C), the registration of any registrant under this title to manufacture, distribute, or dispense controlled substances or list I chemicals terminates if and when such registrant—

(i) dies;

(ii) ceases legal existence;

(iii) discontinues business or professional practice; or

(iv) surrenders such registration.

(B) In the case of such a registrant who ceases legal existence or discontinues business or professional practice, such registrant shall promptly notify the Attorney General in writing of such fact.

(C) No registration under this title to manufacture, distribute, or dispense controlled substances or list I chemicals, and no authority conferred thereby, may be assigned or otherwise transferred except upon such conditions as the Attorney General may specify and then only pursuant to written consent. A registrant to whom a registration is assigned or transferred pursuant to the preceding sentence may not manufacture, distribute, or dispense controlled substances or list I chemicals pursuant to such registration until the Attorney General receives such written consent.

(D) In the case of a registrant under this title to manufacture, distribute, or dispense controlled substances or list I chemicals desiring to discontinue business or professional practice altogether or with respect to controlled substances and list I chemicals (without assigning or transferring such business or professional practice to another entity), such registrant shall return to the Attorney General for cancellation—

(i) the registrant's certificate of registration;

(ii) any unexecuted order forms in the registrant's possession; and

"list I chemical". Piperidine and its salts are currently included as list I chemicals. See section 102(34)(J).

Section 2(a) of such Public Law also replaced the term "listed essential chemical" with the term "list II chemical".

(iii) any other documentation that the Attorney General may require.

(b) 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) 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).[30]

(d) 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)(1) 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.

(2) Notwithstanding paragraph (1), a registrant who is a veterinarian shall not be required to have a separate registration in order to transport and dispense controlled substances in the usual course of veterinary practice at a site other than the registrant's registered principal place of business or professional practice, so long as the site of transporting and dispensing is located in a State where the veterinarian is licensed to practice veterinary medicine and is not a principal place of business or professional practice.

(3) Notwithstanding paragraph (1), a registrant that is dispensing pursuant to section 303(g) narcotic drugs to individuals for maintenance treatment or detoxification treatment shall not be required to have a separate registration to incorporate one or more mobile medication units into the registrant's practice to dispense such narcotics at locations other than the registrant's principal place of business or professional practice described in paragraph (1), so long as the registrant meets such standards for operation of a mobile medication unit as the Attorney General may establish.

(f) 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.

[30] So in law. Probably should be "102(27)". Former paragraph (25) of section 102 was redesignated as paragraph (26) by section 507(a) of Public Law 98–473 (98 Stat. 2071), and section 1003(b)(2) of Public Law 99–570 (100 Stat. 3207–6) redesignated paragraph (26) as paragraph (27).

(g)(1) An ultimate user who has lawfully obtained a controlled substance in accordance with this title may, without being registered, deliver the controlled substance to another person for the purpose of disposal of the controlled substance if—

(A) the person receiving the controlled substance is authorized under this title to engage in such activity; and

(B) the disposal takes place in accordance with regulations issued by the Attorney General to prevent diversion of controlled substances.

(2) In developing regulations under this subsection, the Attorney General shall take into consideration the public health and safety, as well as the ease and cost of program implementation and participation by various communities. Such regulations may not require any entity to establish or operate a delivery or disposal program.

(3) The Attorney General may, by regulation, authorize long-term care facilities, as defined by the Attorney General by regulation, to dispose of controlled substances on behalf of ultimate users who reside, or have resided, at such long-term care facilities in a manner that the Attorney General determines will provide effective controls against diversion and be consistent with the public health and safety.

(4) If a person dies while lawfully in possession of a controlled substance for personal use, any person lawfully entitled to dispose of the decedent's property may deliver the controlled substance to another person for the purpose of disposal under the same conditions as provided in paragraph (1) for an ultimate user.

(5)(A) In the case of a person receiving hospice care, an employee of a qualified hospice program, acting within the scope of employment, may handle, without being registered under this section, any controlled substance that was lawfully dispensed to the person receiving hospice care, for the purpose of disposal of the controlled substance so long as such disposal occurs onsite in accordance with all applicable Federal, State, Tribal, and local law and—

(i) the disposal occurs after the death of a person receiving hospice care;

(ii) the controlled substance is expired; or

(iii)(I) the employee is—

(aa)[31] the physician of the person receiving hospice care; and

(bb)[31] registered under section 303(g); and

(II)[31] the hospice patient no longer requires the controlled substance because the plan of care of the hospice patient has been modified.

(B) For the purposes of this paragraph:

(i) The terms "hospice care" and "hospice program" have the meanings given to those terms in section 1861(dd) of the Social Security Act.

(ii) The term "employee of a qualified hospice program" means a physician, physician assistant, nurse, or other person who—

[31] The margins for items (aa) and (bb) and subclause (II) are so in law.

(I) is employed by, or pursuant to arrangements made by, a qualified hospice program;

(II)(aa) is licensed to perform medical or nursing services by the jurisdiction in which the person receiving hospice care was located; and

(bb) is acting within the scope of such employment in accordance with applicable State law; and

(III) has completed training through the qualified hospice program regarding the disposal of controlled substances in a secure and responsible manner so as to discourage abuse, misuse, or diversion.

(iii) The term "qualified hospice program" means a hospice program that—

(I) has written policies and procedures for assisting in the disposal of the controlled substances of a person receiving hospice care after the person's death;

(II) at the time when the controlled substances are first ordered—

(aa) provides a copy of the written policies and procedures to the patient or patient representative and family;

(bb) discusses the policies and procedures with the patient or representative and the family in a language and manner that they understand to ensure that these parties are educated regarding the safe disposal of controlled substances; and

(cc) documents in the patient's clinical record that the written policies and procedures were provided and discussed; and

(III) at the time following the disposal of the controlled substances—

(aa) documents in the patient's clinical record the type of controlled substance, dosage, route of administration, and quantity so disposed; and

(bb) the time, date, and manner in which that disposal occurred.

REGISTRATION REQUIREMENTS

SEC. 303. [21 U.S.C. 823] (a) 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 sub-

stances 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) 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 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.

(c)(1)(A) As it relates to applications to manufacture marijuana for research purposes, when the Attorney General places a notice in the Federal Register to increase the number of entities registered under this Act to manufacture marijuana to supply appropriately registered researchers in the United States, the Attorney General shall, not later than 60 days after the date on which the Attorney General receives a completed application—

(i) approve the application; or

(ii) request supplemental information.

(B) For purposes of subparagraph (A), an application shall be deemed complete when the applicant has submitted documentation showing each of the following:

(i) The requirements designated in the notice in the Federal Register are satisfied.

(ii) The requirements under this Act are satisfied.

(iii) The applicant will limit the transfer and sale of any marijuana manufactured under this subsection—

(I) to researchers who are registered under this Act to conduct research with controlled substances in schedule I; and

(II) for purposes of use in preclinical research or in a clinical investigation pursuant to an investigational new drug exemption under 505(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(i)).

(iv) The applicant will transfer or sell any marijuana manufactured under this subsection only with prior, written consent for the transfer or sale by the Attorney General.

(v) The applicant has completed the application and review process under subsection (a) for the bulk manufacture of controlled substances in schedule I.

(vi) The applicant has established and begun operation of a process for storage and handling of controlled substances in schedule I, including for inventory control and monitoring security in accordance with section 105 of the Medical Marijuana and Cannabidiol Research Expansion Act.

(vii) The applicant is licensed by each State in which the applicant will conduct operations under this subsection, to manufacture marijuana, if that State requires such a license.

(C) Not later than 30 days after the date on which the Attorney General receives supplemental information requested under subparagraph (A)(ii) with respect to an application, the Attorney General shall approve or deny the application.

(2) If an application described in this subsection is denied, the Attorney General shall provide a written explanation of the basis of denial to the applicant.

(d) 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.

(e) 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.

(f) 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.

(g)[32](1) 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 and shall modify the registrations of pharmacies so registered to authorize them to dispense controlled substances by means of the Internet, 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 or such modification of registration if the Attorney General determines that the issuance of such registration or modification would be inconsistent with the public interest. In determining the public interest, the following factors shall be considered:

(A) The recommendation of the appropriate State licensing board or professional disciplinary authority.

(B) The applicant's experience in dispensing, or conducting research with respect to controlled substances.

(C) The applicant's conviction record under Federal or State laws relating to the manufacture, distribution, or dispensing of controlled substances.

(D) Compliance with applicable State, Federal, or local laws relating to controlled substances.

(E) Such other conduct which may threaten the public health and safety.

Separate registration under this part for practitioners engaging in research with controlled substances in schedule II, III, IV, or V, who are already registered under this part in another capacity, shall not be required.

(2)(A) 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).

[32] See footnote to subsection (h) of this section.

(B)(i) The Attorney General shall register a practitioner to conduct research with marijuana (including any derivative, extract, preparation, and compound thereof) if—

(I) the applicant's research protocol has been reviewed and allowed—

(aa) by the Secretary of Health and Human Services under section 505(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(i));

(bb) by the National Institutes of Health or another Federal agency that funds scientific research; or

(cc) pursuant to sections 1301.18 and 1301.32 of title 21, Code of Federal Regulations, or any successors thereto; and

(II) the applicant has demonstrated to the Attorney General that there are effective procedures in place to adequately safeguard against diversion of the controlled substance for legitimate medical or scientific use pursuant to section 105 of the Medical Marijuana and Cannabidiol Research Expansion Act, including demonstrating that the security measures are adequate for storing the quantity of marijuana the applicant would be authorized to possess.

(ii) The Attorney General may deny an application for registration under this subparagraph only if the Attorney General determines that the issuance of the registration would be inconsistent with the public interest. In determining the public interest, the Attorney General shall consider the factors listed in—

(I) subparagraphs (B) through (E) of paragraph (1); and

(II) subparagraph (A) of paragraph (1), if the applicable State requires practitioners conducting research to register with a board or authority described in such subparagraph (A).

(iii)(I) Not later than 60 days after the date on which the Attorney General receives a complete application for registration under this subparagraph, the Attorney General shall—

(aa) approve the application; or

(bb) request supplemental information.

(II) For purposes of subclause (I), an application shall be deemed complete when the applicant has submitted documentation showing that the requirements under clause (i) are satisfied.

(iv) Not later than 30 days after the date on which the Attorney General receives supplemental information as described in clause (iii)(I)(bb) in connection with an application described in this subparagraph, the Attorney General shall approve or deny the application.

(v) If an application described in this subparagraph is denied, the Attorney General shall provide a written explanation of the basis of denial to the applicant.

(vi)(I) If the Attorney General grants an application for registration under clause (i), the registrant may amend or supplement the research protocol without notification to, or review by, the Drug Enforcement Administration if the registrant does not change—

(aa) the quantity or type of marijuana or cannabidiol (including any derivative, extract, preparation, and compound thereof);

(bb) the source of such marijuana or cannabidiol; or

(cc) the conditions under which such marijuana or cannabidiol is stored, tracked, or administered.

(II)(aa) If a registrant under clause (i) seeks to change the type of marijuana or cannabidiol (including any derivative, extract, preparation, and compound thereof), the source of such marijuana or cannabidiol, or the conditions under which such marijuana or cannabidiol is stored, tracked, or administered, the registrant shall notify the Attorney General via registered mail, or an electronic means permitted by the Attorney General, not later than 30 days before implementing an amended or supplemental research protocol.

(bb) A registrant may proceed with an amended or supplemental research protocol described in item (aa) if the Attorney General does not explicitly object during the 30-day period beginning on the date on which the Attorney General receives the notice under item (aa).

(cc) The Attorney General may only object to an amended or supplemental research protocol under this subclause if additional security measures are needed to safeguard against diversion or abuse.

(dd) If a registrant under clause (i) seeks to address additional security measures identified by the Attorney General under item (cc), the registrant shall notify the Attorney General via registered mail, or an electronic means permitted by the Attorney General, not later than 30 days before implementing an amended or supplemental research protocol.

(ee) A registrant may proceed with an amended or supplemental research protocol described in item (dd) if the Attorney General does not explicitly object during the 30-day period beginning on the date on which the Attorney General receives the notice under item (dd).

(III)(aa) If a registrant under clause (i) seeks to change the quantity of marijuana needed for research and the change in quantity does not impact the factors described in item (bb) or (cc) of subclause (I) of this clause, the registrant shall notify the Attorney General via registered mail or using an electronic means permitted by the Attorney General.

(bb) A notification under item (aa) shall include—

(AA) the Drug Enforcement Administration registration number of the registrant;

(BB) the quantity of marijuana or cannabidiol already obtained;

(CC) the quantity of additional marijuana or cannabidiol needed to complete the research; and

(DD) an attestation that the change in quantity does not impact the source of the marijuana or cannabidiol or the conditions under which the marijuana or cannabidiol is stored, tracked, or administered.

(cc) The Attorney General shall ensure that—

(AA) any registered mail return receipt with respect to a notification under item (aa) is submitted for delivery to the registrant providing the notification not later than 3 days after receipt of the notification by the Attorney General; and

(BB) notice of receipt of a notification using an electronic means permitted under item (aa) is provided to the registrant providing the notification not later than 3 days after receipt of the notification by the Attorney General.

(dd)(AA) On and after the date described in subitem (BB), a registrant that submits a notification in accordance with item (aa) may proceed with the research as if the change in quantity has been approved on such date, unless the Attorney General notifies the registrant of an objection described in item (ee).

(BB) The date described in this subitem is the date on which a registrant submitting a notification under item (aa) receives the registered mail return receipt with respect to the notification or the date on which the registrant receives notice that the notification using an electronic means permitted under item (aa) was received by the Attorney General, as the case may be.

(ee) A notification submitted under item (aa) shall be deemed to be approved unless the Attorney General, not later than 10 days after receiving the notification, explicitly objects based on a finding that the change in quantity—

(AA) does impact the source of the marijuana or cannabidiol or the conditions under which the marijuana or cannabidiol is stored, tracked, or administered; or

(BB) necessitates that the registrant implement additional security measures to safeguard against diversion or abuse.

(IV) Nothing in this clause shall limit the authority of the Secretary of Health and Human Services over requirements related to research protocols, including changes in—

(aa) the method of administration of marijuana or cannabidiol;

(bb) the dosing of marijuana or cannabidiol; and

(cc) the number of individuals or patients involved in research.

(3) Article 7 of the Convention on Psychotrophic 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.

(h) [33](1) Except as provided in paragraph (2), 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)—

(A) 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;

[33] Section 1262(a) of division FF of Public Law 117–328 provides for amendments to section 303(g) of the Controlled Substances Act. Certain amendments do not execute in subsection (g), however, they all appear to carry out properly in subsection (h) which are not reflected above in either subsection (g) or (h). Also, see section 103(a)(1) of PL 117–215 (enacted on Dec. 2, 2022) that redesignated subsections (c)-(k) as subsections (d)-(l), which were carried out to such section 303.

(B) if the Attorney General determines that the applicant will comply with standards established by the Attorney General respecting (i) security of stocks of narcotic drugs for such treatment, and (ii) the maintenance of records (in accordance with section 307) on such drugs; and

(C) 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.

(2)(A) Subject to subparagraphs (D) and (J), the requirements of paragraph (1) are waived in the case of the dispensing (including the prescribing), by a practitioner, of narcotic drugs in schedule III, IV, or V or combinations of such drugs if the practitioner meets the conditions specified in subparagraph (B) and the narcotic drugs or combinations of such drugs meet the conditions specified in subparagraph (C).

(B) For purposes of subparagraph (A), the conditions specified in this subparagraph with respect to a practitioner are that, before the initial dispensing of narcotic drugs in schedule III, IV, or V or combinations of such drugs to patients for maintenance or detoxification treatment, the practitioner submit to the Secretary a notification of the intent of the practitioner to begin dispensing the drugs or combinations for such purpose, and that the notification contain the following certifications by the practitioner:

(i) The practitioner is a qualifying practitioner (as defined in subparagraph (G)).

(ii) With respect to patients to whom the practitioner will provide such drugs or combinations of drugs, the practitioner has the capacity to provide directly, by referral, or in such other manner as determined by the Secretary—

(I) all drugs approved by the Food and Drug Administration for the treatment of opioid use disorder, including for maintenance, detoxification, overdose reversal, and relapse prevention; and

(II) appropriate counseling and other appropriate ancillary services.

(iii)(I) The total number of such patients of the practitioner at any one time will not exceed the applicable number. Except as provided in subclause (II), the applicable number is 30.

(II) The applicable number is—

(aa) 100 if, not sooner than 1 year after the date on which the practitioner submitted the initial notification, the practitioner submits a second notification to the Secretary of the need and intent of the practitioner to treat up to 100 patients;

(bb) 100 if the practitioner holds additional credentialing, as defined in section 8.2 of title 42, Code of Federal Regulations (or successor regulations);

(cc) 100 if the practitioner provides medication-assisted treatment (MAT) using covered medications (as such terms are defined in section 8.2 of title 42, Code of Federal Regulations (or successor regulations)) in a qualified prac-

tice setting (as described in section 8.615 of title 42, Code of Federal Regulations (or successor regulations)); or

(dd) 275 if the practitioner meets the requirements specified in sections 8.610 through 8.655 of title 42, Code of Federal Regulations (or successor regulations).

(III) The Secretary may by regulation change such applicable number.

(IV) The Secretary may exclude from the applicable number patients to whom such drugs or combinations of drugs are directly administered by the qualifying practitioner in the office setting.

(C) For purposes of subparagraph (A), the conditions specified in this subparagraph with respect to narcotic drugs in schedule III, IV, or V or combinations of such drugs are as follows:

(i) The drugs or combinations of drugs have, under the Federal Food, Drug, and Cosmetic Act or section 351 of the Public Health Service Act, been approved for use in maintenance or detoxification treatment.

(ii) The drugs or combinations of drugs have not been the subject of an adverse determination. For purposes of this clause, an adverse determination is a determination published in the Federal Register and made by the Secretary, after consultation with the Attorney General, that the use of the drugs or combinations of drugs for maintenance or detoxification treatment requires additional standards respecting the qualifications of practitioners to provide such treatment, or requires standards respecting the quantities of the drugs that may be provided for unsupervised use.

(D)(i) A waiver under subparagraph (A) with respect to a practitioner is not in effect unless (in addition to conditions under subparagraphs (B) and (C)) the following conditions are met:

(I) The notification under subparagraph (B) is in writing and states the name of the practitioner.

(II) The notification identifies the registration issued for the practitioner pursuant to subsection (g).

(III) If the practitioner is a member of a group practice, the notification states the names of the other practitioners in the practice and identifies the registrations issued for the other practitioners pursuant to subsection (g).

(ii) Upon receiving a determination from the Secretary under clause (iii) finding that a practitioner meets all requirements for a waiver under subparagraph (B), the Attorney General shall assign the practitioner involved an identification number under this paragraph for inclusion with the registration issued for the practitioner pursuant to subsection (g). The identification number so assigned shall be appropriate to preserve the confidentiality of patients for whom the practitioner has dispensed narcotic drugs under a waiver under subparagraph (A).

(iii) Not later than 45 days after the date on which the Secretary receives a notification under subparagraph (B), the Secretary shall make a determination of whether the practitioner involved meets all requirements for a waiver under subparagraph (B) and shall forward such determination to the Attorney General. If the Secretary fails to make such determination by the end of the

such 45-day period, the Attorney General shall assign the practitioner an identification number described in clause (ii) at the end of such period.

(E)(i) If a practitioner is not registered under paragraph (1) and, in violation of the conditions specified in subparagraphs (B) through (D), dispenses narcotic drugs in schedule III, IV, or V or combinations of such drugs for maintenance treatment or detoxification treatment, the Attorney General may, for purposes of section 304(a)(4), consider the practitioner to have committed an act that renders the registration of the practitioner pursuant to subsection (g) to be inconsistent with the public interest.

(ii)(I) Upon the expiration of 45 days from the date on which the Secretary receives a notification under subparagraph (B), a practitioner who in good faith submits a notification under subparagraph (B) and reasonably believes that the conditions specified in subparagraphs (B) through (D) have been met shall, in dispensing narcotic drugs in schedule III, IV, or V or combinations of such drugs for maintenance treatment or detoxification treatment, be considered to have a waiver under subparagraph (A) until notified otherwise by the Secretary, except that such a practitioner may commence to prescribe or dispense such narcotic drugs for such purposes prior to the expiration of such 45-day period if it facilitates the treatment of an individual patient and both the Secretary and the Attorney General are notified by the practitioner of the intent to commence prescribing or dispensing such narcotic drugs.

(II) For purposes of subclause (I), the publication in the Federal Register of an adverse determination by the Secretary pursuant to subparagraph (C)(ii) shall (with respect to the narcotic drug or combination involved) be considered to be a notification provided by the Secretary to practitioners, effective upon the expiration of the 30-day period beginning on the date on which the adverse determination is so published.

(F)(i) With respect to the dispensing of narcotic drugs in schedule III, IV, or V or combinations of such drugs to patients for maintenance or detoxification treatment, a practitioner may, in his or her discretion, dispense such drugs or combinations for such treatment under a registration under paragraph (1) or a waiver under subparagraph (A) (subject to meeting the applicable conditions).

(ii) This paragraph may not be construed as having any legal effect on the conditions for obtaining a registration under paragraph (1), including with respect to the number of patients who may be served under such a registration.

(G) For purposes of this paragraph:

(i) The term "group practice" has the meaning given such term in section 1877(h)(4) of the Social Security Act.

(ii) The term "qualifying physician" means a physician who is licensed under State law and who meets one or more of the following conditions:

(I)[34] The physician holds a board certification in addiction psychiatry or addiction medicine from the American Board of Medical Specialties.

[34] Margins for subclauses (I) and (II) are so in law.

(II)[34] The physician holds an addiction certification or board certification from the American Society of Addiction Medicine or the American Board of Addiction Medicine.

(III) The physician holds a board certification in addiction medicine from the American Osteopathic Association.

(IV) The physician has, with respect to the treatment and management of opiate-dependent patients, completed not less than 8 hours of training (through classroom situations, seminars at professional society meetings, electronic communications, or otherwise) that is provided by the American Society of Addiction Medicine, the American Academy of Addiction Psychiatry, the American Medical Association, the American Osteopathic Association, the American Psychiatric Association, or any other organization that the Secretary determines is appropriate for purposes of this subclause. Such training shall include—

(aa) opioid maintenance and detoxification;

(bb) appropriate clinical use of all drugs approved by the Food and Drug Administration for the treatment of opioid use disorder;

(cc) initial and periodic patient assessments (including substance use monitoring);

(dd) individualized treatment planning, overdose reversal, and relapse prevention;

(ee) counseling and recovery support services;

(ff) staffing roles and considerations;

(gg) diversion control; and

(hh) other best practices, as identified by the Secretary.

(V) The physician has participated as an investigator in one or more clinical trials leading to the approval of a narcotic drug in schedule III, IV, or V for maintenance or detoxification treatment, as demonstrated by a statement submitted to the Secretary by the sponsor of such approved drug.

(VI) The physician has such other training or experience as the State medical licensing board (of the State in which the physician will provide maintenance or detoxification treatment) considers to demonstrate the ability of the physician to treat and manage opiate-dependent patients.

(VII) The physician has such other training or experience as the Secretary considers to demonstrate the ability of the physician to treat and manage opiate-dependent patients. Any criteria of the Secretary under this subclause shall be established by regulation. Any such criteria are effective only for 3 years after the date on which the criteria are promulgated, but may be extended for such additional discrete 3-year periods as the Secretary considers appropriate for purposes of this subclause. Such an extension of criteria may only be effectuated through a statement published in the Federal Register by the Secretary during the

30-day period preceding the end of the 3-year period involved.

(VIII)[35] The physician graduated in good standing from an accredited school of allopathic medicine or osteopathic medicine in the United States during the 5-year period immediately preceding the date on which the physician submits to the Secretary a written notification under subparagraph (B) and successfully completed a comprehensive allopathic or osteopathic medicine curriculum or accredited medical residency that—

(aa) included not less than 8 hours of training on treating and managing opioid-dependent patients; and

(bb) included, at a minimum—

(AA) the training described in items (aa) through (gg) of subclause (IV); and

(BB) training with respect to any other best practice the Secretary determines should be included in the curriculum, which may include training on pain management, including assessment and appropriate use of opioid and non-opioid alternatives.

(iii) The term "qualifying practitioner" means—

(I) a qualifying physician, as defined in clause (ii);

(II) a qualifying other practitioner, as defined in clause (iv), who is a nurse practitioner or physician assistant; or

(III) for the period beginning on October 1, 2018, and ending on October 1, 2023, a qualifying other practitioner, as defined in clause (iv), who is a clinical nurse specialist, certified registered nurse anesthetist, or certified nurse midwife.

(iv) The term "qualifying other practitioner" means a nurse practitioner, clinical nurse specialist, certified registered nurse anesthetist, certified nurse midwife, or physician assistant who satisfies each of the following:

(I) The nurse practitioner, clinical nurse specialist, certified registered nurse anesthetist, certified nurse midwife, or physician assistant is licensed under State law to prescribe schedule III, IV, or V medications for the treatment of pain.

(II) The nurse practitioner, clinical nurse specialist, certified registered nurse anesthetist, certified nurse midwife, or physician assistant has—

(aa) completed not fewer than 24 hours of initial training addressing each of the topics listed in clause (ii)(IV) (through classroom situations, seminars at professional society meetings, electronic communications, or otherwise) provided by the American Society of Addiction Medicine, the American Academy of Addiction Psychiatry, the American Medical Association, the American Osteopathic Association, the American Nurses Credentialing Center, the American Psychiatric Association, the American Association of Nurse Practitioners, the American Academy of Physi-

[35] Margin for subclause (VIII) is so in law.

cian Assistants, or any other organization that the Secretary determines is appropriate for purposes of this subclause; or

(bb) has such other training or experience as the Secretary determines will demonstrate the ability of the nurse practitioner, clinical nurse specialist, certified registered nurse anesthetist, certified nurse midwife, or physician assistant to treat and manage opiate-dependent patients.

(III) The nurse practitioner, clinical nurse specialist, certified registered nurse anesthetist, certified nurse midwife, or physician assistant is supervised by, or works in collaboration with, a qualifying physician, if the nurse practitioner, clinical nurse specialist, certified registered nurse anesthetist, certified nurse midwife, or physician assistant is required by State law to prescribe medications for the treatment of opioid use disorder in collaboration with or under the supervision of a physician.

The Secretary may, by regulation, revise the requirements for being a qualifying other practitioner under this clause.

(H)(i) In consultation with the Administrator of the Drug Enforcement Administration, the Administrator of the Substance Abuse and Mental Health Services Administration, the Director of the National Institute on Drug Abuse, and the Commissioner of Food and Drugs, the Secretary shall issue regulations (through notice and comment rulemaking) or issue practice guidelines to address the following:

(I) Approval of additional credentialing bodies and the responsibilities of additional credentialing bodies.

(II) Additional exemptions from the requirements of this paragraph and any regulations under this paragraph.

(III) Such other elements of the requirements under this paragraph as the Secretary determines necessary for purposes of implementing such requirements.

Nothing in such regulations or practice guidelines may authorize any Federal official or employee to exercise supervision or control over the practice of medicine or the manner in which medical services are provided.

(ii) Not later than 18 months after the date of enactment of the Opioid Use Disorder Treatment Expansion and Modernization Act[36], the Secretary shall update the treatment improvement protocol containing best practice guidelines for the treatment of opioid-dependent patients in office-based settings. The Secretary shall update such protocol in consultation with experts in opioid use disorder research and treatment.

(I) Notwithstanding section 708, nothing in this paragraph shall be construed to preempt any State law that—

[36] The date of enactment of the Opioid Use Disorder Treatment Expansion and Modernization Act, referred to in subsection (g)(2)(H)(ii), probably means the date of enactment of Pub. L. 114–198, known as the Comprehensive Addiction and Recovery Act of 2016, which was approved July 22, 2016. The Opioid Use Disorder Treatment Expansion and Modernization Act was H.R. 4981 of the 114th Congress, as introduced on Apr. 18, 2016. Amendatory provisions of H.R. 4981 were incorporated into Pub. L. 114–198, but no such short title was enacted.

(i) permits a qualifying practitioner to dispense narcotic drugs in schedule III, IV, or V, or combinations of such drugs, for maintenance or detoxification treatment in accordance with this paragraph to a total number of patients that is more than 30 or less than the total number applicable to the qualifying practitioner under subparagraph (B)(iii)(II) if a State enacts a law modifying such total number and the Attorney General is notified by the State of such modification; or

(ii) requires a qualifying practitioner to comply with additional requirements relating to the dispensing of narcotic drugs in schedule III, IV, or V, or combinations of such drugs, including requirements relating to the practice setting in which the qualifying practitioner practices and education, training, and reporting requirements.

(i) 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 clause (iv) or (v) of section 102(39)(A). 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.

(j)(1) For purposes of registration to manufacture a controlled substance under subsection (e) for use only in a clinical trial, the Attorney General shall register the applicant, or serve an order to show cause upon the applicant in accordance with section 304(c), not later than 180 days after the date on which the application is accepted for filing.

(2) For purposes of registration to manufacture a controlled substance under subsection (a) for use only in a clinical trial, the Attorney General shall, in accordance with the regulations issued by the Attorney General, issue a notice of application not later than 90 days after the application is accepted for filing. Not later than 90 days after the date on which the period for comment pursuant to such notice ends, the Attorney General shall register the applicant, or serve an order to show cause upon the applicant in accordance with section 304(c), unless the Attorney General has granted a hearing on the application under section 1008(i) of the Controlled Substances Import and Export Act.

(k) EMERGENCY MEDICAL SERVICES THAT ADMINISTER CONTROLLED SUBSTANCES.—

(1) REGISTRATION.—For the purpose of enabling emergency medical services professionals to administer controlled substances in schedule II, III, IV, or V to ultimate users receiving emergency medical services in accordance with the requirements of this subsection, the Attorney General—

(A) shall register an emergency medical services agency if the agency submits an application demonstrating it is authorized to conduct such activity under the laws of each State in which the agency practices; and

(B) may deny an application for such registration if the Attorney General determines that the issuance of such registration would be inconsistent with the requirements of this subsection or the public interest based on the factors listed in subsection (g).

(2) OPTION FOR SINGLE REGISTRATION.—In registering an emergency medical services agency pursuant to paragraph (1), the Attorney General shall allow such agency the option of a single registration in each State where the agency administers controlled substances in lieu of requiring a separate registration for each location of the emergency medical services agency.

(3) HOSPITAL-BASED AGENCY.—If a hospital-based emergency medical services agency is registered under subsection (g), the agency may use the registration of the hospital to administer controlled substances in accordance with this subsection without being registered under this subsection.

(4) ADMINISTRATION OUTSIDE PHYSICAL PRESENCE OF MEDICAL DIRECTOR OR AUTHORIZING MEDICAL PROFESSIONAL.—Emergency medical services professionals of a registered emergency medical services agency may administer controlled substances in schedule II, III, IV, or V outside the physical presence of a medical director or authorizing medical professional in the course of providing emergency medical services if the administration is—

(A) authorized by the law of the State in which it occurs; and

(B) pursuant to—

(i) a standing order that is issued and adopted by one or more medical directors of the agency, including any such order that may be developed by a specific State authority; or

(ii) a verbal order that is—

(I) issued in accordance with a policy of the agency; and

(II) provided by a medical director or authorizing medical professional in response to a request by the emergency medical services professional with respect to a specific patient—

(aa) in the case of a mass casualty incident; or

(bb) to ensure the proper care and treatment of a specific patient.

(5) DELIVERY.—A registered emergency medical services agency may deliver controlled substances from a registered lo-

cation of the agency to an unregistered location of the agency only if the agency—

(A) designates the unregistered location for such delivery; and

(B) notifies the Attorney General at least 30 days prior to first delivering controlled substances to the unregistered location.

(6) STORAGE.—A registered emergency medical services agency may store controlled substances—

(A) at a registered location of the agency;

(B) at any designated location of the agency or in an emergency services vehicle situated at a registered or designated location of the agency; or

(C) in an emergency medical services vehicle used by the agency that is—

(i) traveling from, or returning to, a registered or designated location of the agency in the course of responding to an emergency; or

(ii) otherwise actively in use by the agency under circumstances that provide for security of the controlled substances consistent with the requirements established by regulations of the Attorney General.

(7) NO TREATMENT AS DISTRIBUTION.—The delivery of controlled substances by a registered emergency medical services agency pursuant to this subsection shall not be treated as distribution for purposes of section 308.

(8) RESTOCKING OF EMERGENCY MEDICAL SERVICES VEHICLES AT A HOSPITAL.—Notwithstanding paragraph (13)(J), a registered emergency medical services agency may receive controlled substances from a hospital for purposes of restocking an emergency medical services vehicle following an emergency response, and without being subject to the requirements of section 308, provided all of the following conditions are satisfied:

(A) The registered or designated location of the agency where the vehicle is primarily situated maintains a record of such receipt in accordance with paragraph (9).

(B) The hospital maintains a record of such delivery to the agency in accordance with section 307.

(C) If the vehicle is primarily situated at a designated location, such location notifies the registered location of the agency within 72 hours of the vehicle receiving the controlled substances.

(9) MAINTENANCE OF RECORDS.—

(A) IN GENERAL.—A registered emergency medical services agency shall maintain records in accordance with subsections (a) and (b) of section 307 of all controlled substances that are received, administered, or otherwise disposed of pursuant to the agency's registration, without regard to subsection 307(c)(1)(B).

(B) REQUIREMENTS.—Such records—

(i) shall include records of deliveries of controlled substances between all locations of the agency; and

(ii) shall be maintained, whether electronically or otherwise, at each registered and designated location

of the agency where the controlled substances involved are received, administered, or otherwise disposed of.

(10) OTHER REQUIREMENTS.—A registered emergency medical services agency, under the supervision of a medical director, shall be responsible for ensuring that—

(A) all emergency medical services professionals who administer controlled substances using the agency's registration act in accordance with the requirements of this subsection;

(B) the recordkeeping requirements of paragraph (9) are met with respect to a registered location and each designated location of the agency;

(C) the applicable physical security requirements established by regulation of the Attorney General are complied with wherever controlled substances are stored by the agency in accordance with paragraph (6); and

(D) the agency maintains, at a registered location of the agency, a record of the standing orders issued or adopted in accordance with paragraph (9).

(11) REGULATIONS.—The Attorney General may issue regulations—

(A) specifying, with regard to delivery of controlled substances under paragraph (5)—

(i) the types of locations that may be designated under such paragraph; and

(ii) the manner in which a notification under paragraph (5)(B) must be made;

(B) specifying, with regard to the storage of controlled substances under paragraph (6), the manner in which such substances must be stored at registered and designated locations, including in emergency medical service vehicles; and

(C) addressing the ability of hospitals, emergency medical services agencies, registered locations, and designated locations to deliver controlled substances to each other in the event of—

(i) shortages of such substances;

(ii) a public health emergency; or

(iii) a mass casualty event.

(12) RULE OF CONSTRUCTION.—Nothing in this subsection shall be construed—

(A) to limit the authority vested in the Attorney General by other provisions of this title to take measures to prevent diversion of controlled substances; or

(B) to override the authority of any State to regulate the provision of emergency medical services consistent with this subsection.

(13) DEFINITIONS.—In this section:

(A) The term "authorizing medical professional" means an emergency or other physician, or another medical professional (including an advanced practice registered nurse or physician assistant)—

(i) who is registered under this Act;

(ii) who is acting within the scope of the registration; and

(iii) whose scope of practice under a State license or certification includes the ability to provide verbal orders.

(B) The term "designated location" means a location designated by an emergency medical services agency under paragraph (5).

(C) The term "emergency medical services" means emergency medical response and emergency mobile medical services provided outside of a fixed medical facility.

(D) The term "emergency medical services agency" means an organization providing emergency medical services, including such an organization that—

(i) is governmental (including fire-based and hospital-based agencies), nongovernmental (including hospital-based agencies), private, or volunteer-based;

(ii) provides emergency medical services by ground, air, or otherwise; and

(iii) is authorized by the State in which the organization is providing such services to provide emergency medical care, including the administering of controlled substances, to members of the general public on an emergency basis.

(E) The term "emergency medical services professional" means a health care professional (including a nurse, paramedic, or emergency medical technician) licensed or certified by the State in which the professional practices and credentialed by a medical director of the respective emergency medical services agency to provide emergency medical services within the scope of the professional's State license or certification.

(F) The term "emergency medical services vehicle" means an ambulance, fire apparatus, supervisor truck, or other vehicle used by an emergency medical services agency for the purpose of providing or facilitating emergency medical care and transport or transporting controlled substances to and from the registered and designated locations.

(G) The term "hospital-based" means, with respect to an agency, owned or operated by a hospital.

(H) The term "medical director" means a physician who is registered under subsection (g) and provides medical oversight for an emergency medical services agency.

(I) The term "medical oversight" means supervision of the provision of medical care by an emergency medical services agency.

(J) The term "registered emergency medical services agency" means—

(i) an emergency medical services agency that is registered pursuant to this subsection; or

(ii) a hospital-based emergency medical services agency that is covered by the registration of the hospital under subsection (g).

(K) The term "registered location" means a location that appears on the certificate of registration issued to an emergency medical services agency under this subsection or subsection (g), which shall be where the agency receives controlled substances from distributors.

(L) The term "specific State authority" means a governmental agency or other such authority, including a regional oversight and coordinating body, that, pursuant to State law or regulation, develops clinical protocols regarding the delivery of emergency medical services in the geographic jurisdiction of such agency or authority within the State that may be adopted by medical directors.

(M) The term "standing order" means a written medical protocol in which a medical director determines in advance the medical criteria that must be met before administering controlled substances to individuals in need of emergency medical services.

(N) The term "verbal order" means an oral directive that is given through any method of communication including by radio or telephone, directly to an emergency medical services professional, to contemporaneously administer a controlled substance to individuals in need of emergency medical services outside the physical presence of the medical director or authorizing medical professional.

(l)[37] In this section, the phrase "factors as may be relevant to and consistent with the public health and safety" means factors that are relevant to and consistent with the findings contained in section 101.

(l)[37] REQUIRED TRAINING FOR PRESCRIBERS.—

(1) TRAINING REQUIRED.—As a condition on registration under this section to dispense controlled substances in schedule II, III, IV, or V, the Attorney General shall require any qualified practitioner, beginning with the first applicable registration for the practitioner, to meet the following:

(A) If the practitioner is a physician (as defined under section 1861(r) of the Social Security Act) and the practitioner meets one or more of the following conditions:

(i) The physician holds a board certification in addiction psychiatry or addiction medicine from the American Board of Medical Specialties.

(ii) The physician holds a board certification from the American Board of Addiction Medicine.

(iii) The physician holds a board certification in addiction medicine from the American Osteopathic Association.

(iv) The physician has, with respect to the treatment and management of patients with opioid or other substance use disorders, or the safe pharmacological management of dental pain and screening, brief intervention, and referral for appropriate treatment of patients with or at risk of developing opioid or other sub-

[37] There are two subsection (l)s' in law. See amendments made by section 103(a)(1) of PL 117-215 which redesignates subsections (c)-(k) as subsections (d)-(l) and section 1263(a) of division FF of Public Law 117–328.

stance use disorders, completed not less than 8 hours of training (through classroom situations, seminars at professional society meetings, electronic communications, or otherwise) that is provided by—

(I) the American Society of Addiction Medicine, the American Academy of Addiction Psychiatry, the American Medical Association, the American Osteopathic Association, the American Dental Association, the American Association of Oral and Maxillofacial Surgeons, the American Psychiatric Association, or any other organization accredited by the Accreditation Council for Continuing Medical Education (ACCME) or the Commission for Continuing Education Provider Recognition (CCEPR);

(II) any organization accredited by a State medical society accreditor that is recognized by the ACCME or the CCEPR;

(III) any organization accredited by the American Osteopathic Association to provide continuing medical education; or

(IV) any organization approved by the Assistant Secretary for Mental Health and Substance Use, the ACCME, or the CCEPR.

(v) The physician graduated in good standing from an accredited school of allopathic medicine, osteopathic medicine, dental surgery, or dental medicine in the United States during the 5-year period immediately preceding the date on which the physician first registers or renews under this section and has successfully completed a comprehensive allopathic or osteopathic medicine curriculum or accredited medical residency or dental surgery or dental medicine curriculum that included not less than 8 hours of training on—

(I) treating and managing patients with opioid or other substance use disorders, including the appropriate clinical use of all drugs approved by the Food and Drug Administration for the treatment of a substance use disorder; or

(II) the safe pharmacological management of dental pain and screening, brief intervention, and referral for appropriate treatment of patients with or at risk of developing opioid and other substance use disorders.

(B) If the practitioner is not a physician (as defined under section 1861(r) of the Social Security Act), the practitioner is legally authorized by the State to dispense controlled substances under schedule II, III, IV, or V and is dispensing such substances within such State in accordance with all applicable State laws, and the practitioner meets one or more of the following conditions:

(i) The practitioner has completed not fewer than 8 hours of training with respect to the treatment and management of patients with opioid or other sub-

stance use disorders (through classroom situations, seminars at professional society meetings, electronic communications, or otherwise) provided by the American Society of Addiction Medicine, the American Academy of Addiction Psychiatry, the American Medical Association, the American Osteopathic Association, the American Nurses Credentialing Center, the American Psychiatric Association, the American Association of Nurse Practitioners, the American Academy of Physician Associates, or any other organization approved or accredited by the Assistant Secretary for Mental Health and Substance Use or the Accreditation Council for Continuing Medical Education.

(ii) The practitioner has graduated in good standing from an accredited physician assistant school or accredited school of advanced practice nursing in the United States during the 5-year period immediately preceding the date on which the practitioner first registers or renews under this section and has successfully completed a comprehensive physician assistant or advanced practice nursing curriculum that included not fewer than 8 hours of training on treating and managing patients with opioid and other substance use disorders, including the appropriate clinical use of all drugs approved by the Food and Drug Administration for the treatment of a substance use disorder.

(2) ONE-TIME TRAINING.—

(A) IN GENERAL.—The Attorney General shall not require any qualified practitioner to complete the training described in clause (iv) or (v) of paragraph (1)(A) or clause (i) or (ii) of paragraph (1)(B) more than once.

(B) NOTIFICATION.—Not later than 90 days after the date of the enactment of the Restoring Hope for Mental Health and Well-Being Act of 2022, the Attorney General shall provide to qualified practitioners a single written, electronic notification of the training described in clauses (iv) and (v) of paragraph (1)(A) or clauses (i) and (ii) of paragraph (1)(B).

(3) RULE OF CONSTRUCTION.—Nothing in this subsection shall be construed—

(A) to preclude the use, by a qualified practitioner, of training received pursuant to this subsection to satisfy registration requirements of a State or for some other lawful purpose; or

(B) to preempt any additional requirements by a State related to the dispensing of controlled substances under schedule II, III, IV, or V.

(4) DEFINITIONS.—In this section:

(A) FIRST APPLICABLE REGISTRATION.—The term "first applicable registration" means the first registration or renewal of registration by a qualified practitioner under this section that occurs on or after the date that is 180 days after the date of enactment of the Restoring Hope for Mental Health and Well-Being Act of 2022.

(B) QUALIFIED PRACTITIONER.—In this subsection, the term "qualified practitioner" means a practitioner who—

(i) is licensed under State law to prescribe controlled substances; and

(ii) is not solely a veterinarian.

DENIAL, REVOCATION, OR SUSPENSION OF REGISTRATION

SEC. 304. [21 U.S.C. 824]

(a)[38] A registration pursuant to section 303 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 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.

A registration pursuant to section 303(h)(1) 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(h)(1).

(b) 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)(1) Before taking action pursuant to this section, or pursuant to a denial of registration under section 303, the Attorney General shall serve upon the applicant or registrant an order to show cause why registration should not be denied, revoked, or suspended.

(2) An order to show cause under paragraph (1) shall—

(A) contain a statement of the basis for the denial, revocation, or suspension, including specific citations to any laws or regulations alleged to be violated by the applicant or registrant;

[38] Section 1262(b)(1) of division FF of Public Law 117–328 attempts to amend subsections (a) and (d)(1) by striking "303(g)(1)" each place it appears and inserting "303(g)". The phrase in the stricken matter does not appear in law and therefore could not be carried out. Such amendment probably should have been to strike "303(h)(1)" and insert "303(h)". See footnote to section 303(h) of this Act.

(B) direct the applicant or registrant to appear before the Attorney General at a time and place stated in the order, but not less than 30 days after the date of receipt of the order; and

(C) notify the applicant or registrant of the opportunity to submit a corrective action plan on or before the date of appearance.

(3) Upon review of any corrective action plan submitted by an applicant or registrant pursuant to paragraph (2), the Attorney General shall determine whether denial, revocation, or suspension proceedings should be discontinued, or deferred for the purposes of modification, amendment, or clarification to such plan.

(4) Proceedings to deny, revoke, or suspend shall be conducted pursuant to this section in accordance with subchapter II of chapter 5 of title 5, United States Code. 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.

(5) The requirements of this subsection shall not apply to the issuance of an immediate suspension order under subsection (d).

(d)(1) 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(h)(1)[38] 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.

(2) In this subsection, the phrase "imminent danger to the public health or safety" means that, due to the failure of the registrant to maintain effective controls against diversion or otherwise comply with the obligations of a registrant under this title or title III, there is a substantial likelihood of an immediate threat that death, serious bodily harm, or abuse of a controlled substance will occur in the absence of an immediate suspension of the registration.

(e) The suspension or revocation of a registration under this section shall operate to suspend or revoke any quota applicable under section 306.

(f) In the event the Attorney General suspends or revokes a registration granted under section 303, 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). 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) The Attorney General may, in his discretion, seize or place under seal any controlled substances or list I chemicals owned or possesed 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 substances or list I chemicals 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.

(h) The Attorney General may issue an order to prohibit, conditionally or unconditionally, and permanently or for such period as the Attorney General may determine, any person from being registered under this title to manufacture, distribute, or dispense a controlled substance or a list I chemical, if the Attorney General finds that—

(1) such person meets or has met any of the conditions for suspension or revocation of registration under subsection (a); and

(2) such person has a history of prior suspensions or revocations of registration.

LABELING AND PACKAGING REQUIREMENTS

SEC. 305. [21 U.S.C. 825] (a) 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) 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) It shall be unlawful for the manufacturer of any controlled substance to distribute such substances unless the labeling (as defined in section 201(m) of the Federal Food, Drug, and Cosmetic Act) of such substance contains, when and as required by regulations of the Attorney General, the identifying symbol required under subsection (a).

(c) The Secretary shall prescribe regulations under section 503(b) of the Federal Food, Drug, and Cosmetic Act 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) 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.

(e) FALSE LABELING OF ANABOLIC STEROIDS.—

(1) It shall be unlawful to import, export, manufacture, distribute, dispense, or possess with intent to manufacture, distribute, or dispense, an anabolic steroid or product containing an anabolic steroid, unless the steroid or product bears a label clearly identifying an anabolic steroid or product containing an anabolic steroid by the nomenclature used by the International Union of Pure and Applied Chemistry (IUPAC).

(2)(A) A product described in subparagraph (B) is exempt from the International Union of Pure and Applied Chemistry nomenclature requirement of this subsection if such product is labeled in the manner required under the Federal Food, Drug, and Cosmetic Act.

(B) A product is described in this subparagraph if the product—

(i) is the subject of an approved application as described in section 505(b) or (j) of the Federal Food, Drug, and Cosmetic Act; or

(ii) is exempt from the provisions of section 505 of such Act relating to new drugs because—

(I) it is intended solely for investigational use as described in section 505(i) of such Act; and

(II) such product is being used exclusively for purposes of a clinical trial that is the subject of an effective investigational new drug application.

QUOTAS APPLICABLE TO CERTAIN SUBSTANCES

SEC. 306. [21 U.S.C. 826] (a)(1) The Attorney General shall determine the total quantity and establish production quotas for each basic class of controlled substance in schedules I and II and for ephedrine, pseudoephedrine, and phenylpropanolamine 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. Except as provided in paragraph (2), 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.

(2) The Attorney General may, if the Attorney General determines it will assist in avoiding the overproduction, shortages, or diversion of a controlled substance, establish an aggregate or individual production quota under this subsection, or a procurement quota established by the Attorney General by regulation, in terms of pharmaceutical dosage forms prepared from or containing the controlled substance.

(b) The Attorney General shall limit or reduce individual manufacturing 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 or for ephedrine, pseudoephedrine, or phenylpropanolamine 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) On or before December 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 and for ephedrine, pseudoephedrine, and phenylpropanolamine 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) 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 or ephedrine, pseudoephedrine, or phenylpropanolamine 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) 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 or for ephedrine, pseudoephedrine, or phenylpropanolamine 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) 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 or ephedrine, pseudoephedrine, or phenylpropanolamine as incidentally and necessarily result from the manufacturing process used for the

manufacture of a controlled substance or of ephedrine, pseudoephedrine, or phenylpropanolamine 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 or chemicals.

(g) Each reference in this section to ephedrine, pseudoephedrine, or phenylpropanolamine includes each of the salts, optical isomers, and salts of optical isomers of such chemical.

(h)(1) Not later than 30 days after the receipt of a request described in paragraph (2), the Attorney General shall—

(A) complete review of such request; and

(B)(i) as necessary to address a shortage of a controlled substance, increase the aggregate and individual production quotas under this section applicable to such controlled substance and any ingredient therein to the level requested; or

(ii) if the Attorney General determines that the level requested is not necessary to address a shortage of a controlled substance, the Attorney General shall provide a written response detailing the basis for the Attorney General's determination.

The Secretary shall make the written response provided under subparagraph (B)(ii) available to the public on the Internet Web site of the Food and Drug Administration.

(2) A request is described in this paragraph if—

(A) the request pertains to a controlled substance on the list of drugs in shortage maintained under section 506E of the Federal Food, Drug, and Cosmetic Act;

(B) the request is submitted by the manufacturer of the controlled substance; and

(C) the controlled substance is in schedule II.

(i)(1)(A) In establishing any quota under this section, or any procurement quota established by the Attorney General by regulation, for fentanyl, oxycodone, hydrocodone, oxymorphone, or hydromorphone (in this subsection referred to as a "covered controlled substance"), the Attorney General shall estimate the amount of diversion of the covered controlled substance that occurs in the United States.

(B) In estimating diversion under this paragraph, the Attorney General—

(i) shall consider information the Attorney General, in consultation with the Secretary of Health and Human Services, determines reliable on rates of overdose deaths and abuse and overall public health impact related to the covered controlled substance in the United States; and

(ii) may take into consideration whatever other sources of information the Attorney General determines reliable.

(C) After estimating the amount of diversion of a covered controlled substance, the Attorney General shall make appropriate quota reductions, as determined by the Attorney General, from the quota the Attorney General would have otherwise established had such diversion not been considered.

(2)(A) For any year for which the approved aggregate production quota for a covered controlled substance is higher than the approved aggregate production quota for the covered controlled sub-

stance for the previous year, the Attorney General, in consultation with the Secretary of Health and Human Services, shall include in the final order an explanation of why the public health benefits of increasing the quota clearly outweigh the consequences of having an increased volume of the covered controlled substance available for sale, and potential diversion, in the United States.

(B) Not later than 1 year after the date of enactment of this subsection, and every year thereafter, the Attorney General shall submit to the Committee on the Judiciary, the Committee on Health, Education, Labor, and Pensions, and the Committee on Appropriations of the Senate and the Committee on the Judiciary, the Committee on Energy and Commerce, and the Committee on Appropriations of the House of Representatives the following information with regard to each covered controlled substance:

(i) An anonymized count of the total number of manufacturers issued individual manufacturing quotas that year for the covered controlled substance.

(ii) An anonymized count of how many such manufacturers were issued an approved manufacturing quota that was higher than the quota issued to that manufacturer for the covered controlled substance in the previous year.

(3) Not later than 1 year after the date of enactment of this subsection, the Attorney General shall submit to Congress a report on how the Attorney General, when fixing and adjusting production and manufacturing quotas under this section for covered controlled substances, will—

(A) take into consideration changes in the accepted medical use of the covered controlled substances; and

(B) work with the Secretary of Health and Human Services on methods to appropriately and anonymously estimate the type and amount of covered controlled substances that are submitted for collection from approved drug collection receptacles, mail-back programs, and take-back events.

RECORDS AND REPORTS OF REGISTRANTS

SEC. 307. [21 U.S.C. 827] (a) 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) 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) 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;

(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. [39]

[39] Sentence at end of subsection (c), and subsection (e) in its entirety, were added by title I of Public Law 95–633. Section 112 of such Public Law provided as follows: "This title shall take effect on the date the Convention on Psychotropic Substances, signed at Vienna, Austria on Feb-

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(d)(1) Every manufacturer registered under section 303 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) to whom such sale, delivery, or other disposal was made.

(2) Each pharmacy with a modified registration under section 303(g) that authorizes the dispensing of controlled substances by means of the Internet shall report to the Attorney General the controlled substances it dispenses, in the amount specified, and in such time and manner as the Attorney General by regulation shall require, except that the Attorney General, under this paragraph, may not require any pharmacy to report any information other than the total quantity of each controlled substance that the pharmacy has dispensed each month. For purposes of this paragraph, no reporting shall be required unless the pharmacy has met 1 of the following thresholds in the month for which the reporting is required:

(A) 100 or more prescriptions dispensed.

(B) 5,000 or more dosage units of all controlled substances combined.

(e)[39] In addition to the reporting and recordkeeping requirements under any other provision of this title, each manufacturer registered under section 303 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)(1) The Attorney General shall, not less frequently than quarterly, make the following information available to manufacturer and distributor registrants through the Automated Reports and Consolidated Orders System, or any subsequent automated system developed by the Drug Enforcement Administration to monitor selected controlled substances:

(A) The total number of distributor registrants that distribute controlled substances to a pharmacy or practitioner registrant, aggregated by the name and address of each pharmacy and practitioner registrant.

(B) The total quantity and type of opioids distributed, listed by Administration Controlled Substances Code Number, to each pharmacy and practitioner registrant described in subparagraph (A).

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ruary 21, 1971, enters into force in respect to the United States.". The Convention entered into force in respect to the United States on July 15, 1980.

(2) The information required to be made available under paragraph (1) shall be made available not later than the 30th day of the first month following the quarter to which the information relates.

(3)(A) All registered manufacturers and distributors shall be responsible for reviewing the information made available by the Attorney General under this subsection.

(B) In determining whether to initiate proceedings under this title against a registered manufacturer or distributor based on the failure of the registrant to maintain effective controls against diversion or otherwise comply with the requirements of this title or the regulations issued thereunder, the Attorney General may take into account that the information made available under this subsection was available to the registrant.

(g) Regulations under sections 505(i) and 512(j) of the Federal Food, Drug, and Cosmetic Act, 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.

(h) 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.

(i) In the case of a drug product containing gamma hydroxybutyric acid for which an application has been approved under section 505 of the Federal Food, Drug, and Cosmetic Act, the Attorney General may, in addition to any other requirements that apply under this section with respect to such a drug product, establish any of the following as reporting requirements:

(1) That every person who is registered as a manufacturer of bulk or dosage form, as a packager, repackager, labeler, relabeler, or distributor shall report acquisition and distribution transactions quarterly, not later than the 15th day of the month succeeding the quarter for which the report is submitted, and annually report end-of-year inventories.

(2) That all annual inventory reports shall be filed no later than January 15 of the year following that for which the report is submitted and include data on the stocks of the drug product, drug substance, bulk drug, and dosage forms on hand as of the close of business December 31, indicating whether materials reported are in storage or in process of manufacturing.

(3) That every person who is registered as a manufacturer of bulk or dosage form shall report all manufacturing transactions both inventory increases, including purchases, transfers, and returns, and reductions from inventory, including sales, transfers, theft, destruction, and seizure, and shall provide data on material manufactured, manufactured from other material, use in manufacturing other material, and use in manufacturing dosage forms.

(4) That all reports under this section must include the registered person's registration number as well as the registration numbers, names, and other identifying information of vendors, suppliers, and customers, sufficient to allow the Attorney General to track the receipt and distribution of the drug.

(5) That each dispensing practitioner shall maintain for each prescription the name of the prescribing practitioner, the prescribing practitioner's Federal and State registration numbers, with the expiration dates of these registrations, verification that the prescribing practitioner possesses the appropriate registration to prescribe this controlled substance, the patient's name and address, the name of the patient's insurance provider and documentation by a medical practitioner licensed and registered to prescribe the drug of the patient's medical need for the drug. Such information shall be available for inspection and copying by the Attorney General.

(6) That section 310(b)(3) (relating to mail order reporting) applies with respect to gamma hydroxybutyric acid to the same extent and in the same manner as such section applies with respect to the chemicals and drug products specified in subparagraph (A)(i) of such section.

(j) All of the reports required under this section shall be provided in an electronic format.

ORDER FORMS

SEC. 308. [21 U.S.C. 828] (a) 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) 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); or

(3) the delivery of such a substance for the purpose of disposal by an ultimate user, long-term care facility, or other person acting in accordance with section 302(g).

(c)(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 Attor-

ney 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)(1) The Attorney General shall issue forms pursuant to subsections (a) and (c)(2) only to persons validly registered under section 303 (or exempted from registration under section 302(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) 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.

PRESCRIPTIONS

SEC. 309. [21 U.S.C. 829] (a) 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, 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. Prescriptions shall be retained in conformity with the requirements of section 307 of this title. No prescription for a controlled substance in schedule II may be refilled.

(b) 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, may be dispensed without a written or oral prescription in conformity with section 503(b) of that Act. 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) No controlled substance in schedule V which is a drug may be distributed or dispensed other than for a medical purpose.

(d) 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 should be so considered because of its abuse potential, he shall so advise the Secretary and furnish to him all available data relevant thereto.

(e) CONTROLLED SUBSTANCES DISPENSED BY MEANS OF THE INTERNET.—

(1) No controlled substance that is a prescription drug as determined under the Federal Food, Drug, and Cosmetic Act may be delivered, distributed, or dispensed by means of the Internet without a valid prescription.

(2) As used in this subsection:

(A) The term "valid prescription" means a prescription that is issued for a legitimate medical purpose in the usual course of professional practice by—

(i) a practitioner who has conducted at least 1 in-person medical evaluation of the patient; or

(ii) a covering practitioner.

(B)(i) The term "in-person medical evaluation" means a medical evaluation that is conducted with the patient in the physical presence of the practitioner, without regard to whether portions of the evaluation are conducted by other health professionals.

(ii) Nothing in clause (i) shall be construed to imply that 1 in-person medical evaluation demonstrates that a prescription has been issued for a legitimate medical purpose within the usual course of professional practice.

(C) The term "covering practitioner" means, with respect to a patient, a practitioner who conducts a medical evaluation (other than an in-person medical evaluation) at the request of a practitioner who—

(i) has conducted at least 1 in-person medical evaluation of the patient or an evaluation of the patient through the practice of telemedicine, within the previous 24 months; and

(ii) is temporarily unavailable to conduct the evaluation of the patient.

(3) Nothing in this subsection shall apply to—

(A) the delivery, distribution, or dispensing of a controlled substance by a practitioner engaged in the practice of telemedicine; or

(B) the dispensing or selling of a controlled substance pursuant to practices as determined by the Attorney General by regulation, which shall be consistent with effective controls against diversion.

(f) PARTIAL FILLS OF SCHEDULE II CONTROLLED SUBSTANCES.—

(1) PARTIAL FILLS.—A prescription for a controlled substance in schedule II may be partially filled if—

(A) it is not prohibited by State law;

(B) the prescription is written and filled in accordance with this title, regulations prescribed by the Attorney General, and State law;

(C) the partial fill is requested by the patient or the practitioner that wrote the prescription; and

(D) the total quantity dispensed in all partial fillings does not exceed the total quantity prescribed.

(2) REMAINING PORTIONS.—

(A) IN GENERAL.—Except as provided in subparagraph (B), remaining portions of a partially filled prescription for a controlled substance in schedule II—

(i) may be filled; and

(ii) shall be filled not later than 30 days after the date on which the prescription is written.

(B) EMERGENCY SITUATIONS.—In emergency situations, as described in subsection (a), the remaining portions of a partially filled prescription for a controlled substance in schedule II—

(i) may be filled; and

(ii) shall be filled not later than 72 hours after the prescription is issued.

(3) CURRENTLY LAWFUL PARTIAL FILLS.—Notwithstanding paragraph (1) or (2), in any circumstance in which, as of the day before the date of enactment of this subsection, a prescription for a controlled substance in schedule II may be lawfully partially filled, the Attorney General may allow such a prescription to be partially filled.

DELIVERY OF A CONTROLLED SUBSTANCE BY A PHARMACY TO AN ADMINISTERING PRACTITIONER

SEC. 309A. [21 U.S.C. 829a] (a) IN GENERAL.—Notwithstanding section 102(10), a pharmacy may deliver a controlled substance to a practitioner in accordance with a prescription that meets the requirements of this title and the regulations issued by the Attorney General under this title, for the purpose of administering the controlled substance by the practitioner if—

(1) the controlled substance is delivered by the pharmacy to the prescribing practitioner or the practitioner administering the controlled substance, as applicable, at the location listed on the practitioner's certificate of registration issued under this title;

(2) the controlled substance is to be administered for the purpose of maintenance or detoxification treatment under section 303(h)(2) [40]and is to be administered by injection or implantation;

(3) the pharmacy and the practitioner are authorized to conduct the activities specified in this section under the law of the State in which such activities take place;

(4) the prescription is not issued to supply any practitioner with a stock of controlled substances for the purpose of general dispensing to patients;

(5) except as provided in subsection (b), the controlled substance is to be administered only to the patient named on the prescription not later than 45 days after the date of receipt of the controlled substance by the practitioner; and

[40] Section 1262(b)(2)(A) of division FF of Public Law 117–328 attempts to amend subsection (a)(2) by striking "the controlled substance is to be administered for the purpose of maintenance or detoxification treatment under section 303(g)(2)" and inserting "the controlled substance is a narcotic drug in schedule III, IV, or V to be administered for the purpose of maintenance or detoxification treatment". The phrase in the stricken matter for "under section 303(g)(2)" should have read "under section 303(h)(2)" and therefore was not carried out above. See footnote to section 303(h) of this Act.

(6) notwithstanding any exceptions under section 307, the prescribing practitioner, and the practitioner administering the controlled substance, as applicable, maintain complete and accurate records of all controlled substances delivered, received, administered, or otherwise disposed of under this section, including the persons to whom controlled substances were delivered and such other information as may be required by regulations of the Attorney General.

(b) MODIFICATION OF NUMBER OF DAYS BEFORE WHICH CONTROLLED SUBSTANCE SHALL BE ADMINISTERED.—

(1) INITIAL 2-YEAR PERIOD.—During the 2-year period beginning on the date of enactment of this section, the Attorney General, in coordination with the Secretary, may reduce the number of days described in subsection (a)(5) if the Attorney General determines that such reduction will—

(A) reduce the risk of diversion; or

(B) protect the public health.

(2) MODIFICATIONS AFTER SUBMISSION OF REPORT.—After the date on which the report described in section 3204(b) of the SUPPORT for Patients and Communities Act is submitted, the Attorney General, in coordination with the Secretary, may modify the number of days described in subsection (a)(5).

(3) MINIMUM NUMBER OF DAYS.—Any modification under this subsection shall be for a period of not less than 7 days.

REGULATION OF LISTED CHEMICALS AND CERTAIN MACHINES

SEC. 310. [21 U.S.C. 830] (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 for two years after the date of the transaction.

(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).

(3) MAIL ORDER REPORTING.—

(A) As used in this paragraph:

(i) The term "drug product" means an active ingredient in dosage form that has been approved or otherwise may be lawfully marketed under the Food, Drug, and Cosmetic Act for distribution in the United States.

(ii) The term "valid prescription" means a prescription which is issued for a legitimate medical purpose by an individual practitioner licensed by law to administer and prescribe the drugs concerned and acting in the usual course of the practitioner's professional practice.

(B) Each regulated person who engages in a transaction with a nonregulated person or who engages in an export transaction which—

(i) involves ephedrine, pseudoephedrine, or phenylpropanolamine (including drug products containing these chemicals); and

(ii) uses or attempts to use the Postal Service or any private or commercial carrier;

shall, on a monthly basis, submit a report of each such transaction conducted during the previous month to the Attorney General in such form, containing such data, and at such times as the Attorney General shall establish by regulation.

(C) The data required for such reports shall include—

(i) the name of the purchaser;

(ii) the quantity and form of the ephedrine, pseudoephedrine, or phenylpropanolamine purchased; and

(iii) the address to which such ephedrine, pseudoephedrine, or phenylpropanolamine was sent.

(D) Except as provided in subparagraph (E), the following distributions to a nonregulated person, and the following export transactions, shall not be subject to the reporting requirement in subparagraph (B):

(i) Distributions of sample packages of drug products when such packages contain not more than two solid dosage units or the equivalent of two dosage units in liquid form, not to exceed 10 milliliters of liquid per package, and not more than one package is distributed to an individual or residential address in any 30-day period.

(ii) Distributions of drug products by retail distributors that may not include face-to-face transactions to the extent that such distributions are consistent with the activities authorized for a retail distributor as specified in section 102(49), except that this clause does not apply to sales of scheduled listed chemical products at retail.

(iii) Distributions of drug products to a resident of a long term care facility (as that term is defined in regulations prescribed by the Attorney General) or distributions of drug products to a long term care facility for dispensing to or for use by a resident of that facility.

(iv) Distributions of drug products pursuant to a valid prescription.

(v) Exports which have been reported to the Attorney General pursuant to section 1004 or 1018 or which are subject to a waiver granted under section 1018(f)(2).

(vi) Any quantity, method, or type of distribution or any quantity, method, or type of distribution of a specific listed chemical (including specific formulations or drug products) or of a group of listed chemicals (including specific formulations or drug products) which the Attorney General has excluded by regulation from such reporting requirement on the basis that such reporting is not necessary for the enforcement of this title or title III.

(E) The Attorney General may revoke any or all of the exemptions listed in subparagraph (D) for an individual regulated person if he finds that drug products distributed by the regulated person are being used in violation of this title or title III. The regulated person shall be notified of the revocation, which will be effective upon receipt by the person of such notice, as provided in section 1018(c)(1), and shall have the right to an expedited hearing as provided in section 1018(c)(2).

(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 customs laws;

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

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.

(d) SCHEDULED LISTED CHEMICALS; RESTRICTIONS ON SALES QUANTITY; REQUIREMENTS REGARDING NONLIQUID FORMS.—With respect to ephedrine base, pseudoephedrine base, or phenylpropanolamine base in a scheduled listed chemical product—

(1) the quantity of such base sold at retail in such a product by a regulated seller, or a distributor required to submit reports by subsection (b)(3) may not, for any purchaser, exceed a daily amount of 3.6 grams, without regard to the number of transactions; and

(2) such a seller or distributor may not sell such a product in nonliquid form (including gel caps) at retail unless the product is packaged in blister packs, each blister containing not more than 2 dosage units, or where the use of blister packs is technically infeasible, the product is packaged in unit dose packets or pouches.

(e) SCHEDULED LISTED CHEMICALS; BEHIND-THE-COUNTER ACCESS; LOGBOOK REQUIREMENT; TRAINING OF SALES PERSONNEL; PRIVACY PROTECTIONS.—

(1) REQUIREMENTS REGARDING RETAIL TRANSACTIONS.—

(A) IN GENERAL.—Each regulated seller shall ensure that, subject to subparagraph (F), sales by such seller of a

scheduled listed chemical product at retail are made in accordance with the following:

(i) In offering the product for sale, the seller places the product such that customers do not have direct access to the product before the sale is made (in this paragraph referred to as "behind-the-counter" placement). For purposes of this paragraph, a behind-the-counter placement of a product includes circumstances in which the product is stored in a locked cabinet that is located in an area of the facility involved to which customers do have direct access.

(ii) The seller delivers the product directly into the custody of the purchaser.

(iii) The seller maintains, in accordance with criteria issued by the Attorney General, a written or electronic list of such sales that identifies the products by name, the quantity sold, the names and addresses of purchasers, and the dates and times of the sales (which list is referred to in this subsection as the "logbook"), except that such requirement does not apply to any purchase by an individual of a single sales package if that package contains not more than 60 milligrams of pseudoephedrine.

(iv) In the case of a sale to which the requirement of clause (iii) applies, the seller does not sell such a product unless the sale is made in accordance with the following:

(I) The prospective purchaser—

(aa) presents an identification card that provides a photograph and is issued by a State or the Federal Government, or a document that, with respect to identification, is considered acceptable for purposes of sections 274a.2(b)(1)(v)(A) and 274a.2(b)(1)(v)(B) of title 8, Code of Federal Regulations (as in effect on or after March 9, 2006); and

(bb) signs the written logbook and enters in the logbook his or her name, address, and the date and time of the sale, or for transactions involving an electronic logbook, the purchaser provides a signature using one of the following means:

(AA) Signing a device presented by the seller that captures signatures in an electronic format. Such device shall display the notice described in clause (v). Any device used shall preserve each signature in a manner that clearly links that signature to the other electronically-captured logbook information relating to the prospective purchaser providing that signature.

(BB) Signing a bound paper book. Such bound paper book shall include, for

such purchaser, either (aaa) a printed sticker affixed to the bound paper book at the time of sale which either displays the name of each product sold, the quantity sold, the name and address of the purchaser, and the date and time of the sale, or a unique identifier which can be linked to that electronic information, or (bbb) a unique identifier which can be linked to that information and which is written into the book by the seller at the time of sale. The purchaser shall sign adjacent to the printed sticker or written unique identifier related to that sale. Such bound paper book shall display the notice described in clause (v).

(CC) Signing a printed document that includes, for such purchaser, the name of each product sold, the quantity sold, the name and address of the purchaser, and the date and time of the sale. Such document shall be printed by the seller at the time of the sale. Such document shall contain a clearly identified signature line for a purchaser to sign. Such printed document shall display the notice described in clause (v). Each signed document shall be inserted into a binder or other secure means of document storage immediately after the purchaser signs the document.

(II) The seller enters in the logbook the name of the product and the quantity sold. Such information may be captured through electronic means, including through electronic data capture through bar code reader or similar technology.

(III) The logbook maintained by the seller includes the prospective purchaser's name, address, and the date and time of the sale, as follows:

(aa) If the purchaser enters the information, the seller must determine that the name entered in the logbook corresponds to the name provided on such identification and that the date and time entered are correct.

(bb) If the seller enters the information, the prospective purchaser must verify that the information is correct.

(cc) Such information may be captured through electronic means, including through electronic data capture through bar code reader or similar technology.

(v) The written or electronic logbook includes, in accordance with criteria of the Attorney General, a notice to purchasers that entering false statements or misrepresentations in the logbook, or supplying false

information or identification that results in the entry of false statements or misrepresentations, may subject the purchasers to criminal penalties under section 1001 of title 18, United States Code, which notice specifies the maximum fine and term of imprisonment under such section.

(vi) Regardless of whether the logbook entry is written or electronic, the seller maintains each entry in the logbook for not fewer than 2 years after the date on which the entry is made.

(vii) In the case of individuals who are responsible for delivering such products into the custody of purchasers or who deal directly with purchasers by obtaining payments for the products, the seller has submitted to the Attorney General a self-certification that all such individuals have, in accordance with criteria under subparagraph (B)(ii), undergone training provided by the seller to ensure that the individuals understand the requirements that apply under this subsection and subsection (d).

(viii) The seller maintains a copy of such certification and records demonstrating that individuals referred to in clause (vii) have undergone the training.

(ix) If the seller is a mobile retail vendor:

(I) The seller complies with clause (i) by placing the product in a locked cabinet.

(II) The seller does not sell more than 7.5 grams of ephedrine base, pseudoephedrine base, or phenylpropanolamine base in such products per customer during a 30-day period.

(B) ADDITIONAL PROVISIONS REGARDING CERTIFICATIONS AND TRAINING.—

(i) IN GENERAL.—A regulated seller may not sell any scheduled listed chemical product at retail unless the seller has submitted to the Attorney General the self-certification referred to in subparagraph (A)(vii). The certification is not effective for purposes of the preceding sentence unless, in addition to provisions regarding the training of individuals referred to in such subparagraph, the certification includes a statement that the seller understands each of the requirements that apply under this paragraph and under subsection (d) and agrees to comply with the requirements.

(ii) ISSUANCE OF CRITERIA; SELF-CERTIFICATION.—The Attorney General shall by regulation establish criteria for certifications under this paragraph. The criteria shall—

(I) provide that the certifications are self-certifications provided through the program under clause (iii);

(II) provide that a separate certification is required for each place of business at which a regulated seller sells scheduled listed chemical products at retail; and

(III) include criteria for training under subparagraph (A)(vii).

(iii) PROGRAM FOR REGULATED SELLERS.—The Attorney General shall establish a program regarding such certifications and training in accordance with the following:

(I) The program shall be carried out through an Internet site of the Department of Justice and such other means as the Attorney General determines to be appropriate.

(II) The program shall inform regulated sellers that section 1001 of title 18, United States Code, applies to such certifications.

(III) The program shall make available to such sellers an explanation of the criteria under clause (ii).

(IV) The program shall be designed to permit the submission of the certifications through such Internet site.

(V) The program shall be designed to automatically provide the explanation referred to in subclause (III), and an acknowledgement that the Department has received a certification, without requiring direct interactions of regulated sellers with staff of the Department (other than the provision of technical assistance, as appropriate).

(iv) AVAILABILITY OF CERTIFICATION TO STATE AND LOCAL OFFICIALS.—Promptly after receiving a certification under subparagraph (A)(vii), the Attorney General shall make available a copy of the certification to the appropriate State and local officials.

(v) PUBLICATION OF LIST OF SELF-CERTIFIED PERSONS.—The Attorney General shall develop and make available a list of all persons who are currently self-certified in accordance with this section. This list shall be made publicly available on the website of the Drug Enforcement Administration in an electronically downloadable format.

(C) PRIVACY PROTECTIONS.—In order to protect the privacy of individuals who purchase scheduled listed chemical products, the Attorney General shall by regulation establish restrictions on disclosure of information in logbooks under subparagraph (A)(iii). Such regulations shall—

(i) provide for the disclosure of the information as appropriate to the Attorney General and to State and local law enforcement agencies; and

(ii) prohibit accessing, using, or sharing information in the logbooks for any purpose other than to ensure compliance with this title or to facilitate a product recall to protect public health and safety.

(D) FALSE STATEMENTS OR MISREPRESENTATIONS BY PURCHASERS.—For purposes of section 1001 of title 18, United States Code, entering information in the logbook under subparagraph (A)(iii) shall be considered a matter

within the jurisdiction of the executive, legislative, or judicial branch of the Government of the United States.

(E) GOOD FAITH PROTECTION.—A regulated seller who in good faith releases information in a logbook under subparagraph (A)(iii) to Federal, State, or local law enforcement authorities is immune from civil liability for such release unless the release constitutes gross negligence or intentional, wanton, or willful misconduct.

(F) INAPPLICABILITY OF REQUIREMENTS TO CERTAIN SALES.—Subparagraph (A) does not apply to the sale at retail of a scheduled listed chemical product if a report on the sales transaction is required to be submitted to the Attorney General under subsection (b)(3).

(G) CERTAIN MEASURES REGARDING THEFT AND DIVERSION.—A regulated seller may take reasonable measures to guard against employing individuals who may present a risk with respect to the theft and diversion of scheduled listed chemical products, which may include, notwithstanding State law, asking applicants for employment whether they have been convicted of any crime involving or related to such products or controlled substances.

(2) MAIL-ORDER REPORTING; VERIFICATION OF IDENTITY OF PURCHASER; 30-DAY RESTRICTION ON QUANTITIES FOR INDIVIDUAL PURCHASERS.—Each regulated person who makes a sale at retail of a scheduled listed chemical product and is required under subsection (b)(3) to submit a report of the sales transaction to the Attorney General is subject to the following:

(A) The person shall, prior to shipping the product, confirm the identity of the purchaser in accordance with procedures established by the Attorney General. The Attorney General shall by regulation establish such procedures.

(B) The person may not sell more than 7.5 grams of ephedrine base, pseudoephedrine base, or phenylpropanolamine base in such products per customer during a 30-day period.

(C) Each regulated person who makes a sale at retail of a scheduled listed chemical product and is required under subsection (b)(3) to submit a report of the sales transaction to the Attorney General may not sell any scheduled listed chemical product at retail unless such regulated person has submitted to the Attorney General a self-certification including a statement that the seller understands each of the requirements that apply under this paragraph and under subsection (d) and agrees to comply with the requirements. The Attorney General shall by regulation establish criteria for certifications of mail-order distributors that are consistent with the criteria established for the certifications of regulated sellers under paragraph (1)(B).

(3) EXEMPTIONS FOR CERTAIN PRODUCTS.—Upon the application of a manufacturer of a scheduled listed chemical product, the Attorney General may by regulation provide that the product is exempt from the provisions of subsection (d) and

paragraphs (1) and (2) of this subsection if the Attorney General determines that the product cannot be used in the illicit manufacture of methamphetamine.

ADDITIONAL REQUIREMENTS RELATING TO ONLINE PHARMACIES AND TELEMEDICINE

SEC. 311. [21 U.S.C. 831] (a) IN GENERAL.—An online pharmacy shall display in a visible and clear manner on its homepage a statement that it complies with the requirements of this section with respect to the delivery or sale or offer for sale of controlled substances and shall at all times display on the homepage of its Internet site a declaration of compliance in accordance with this section.

(b) LICENSURE.—Each online pharmacy shall comply with the requirements of State law concerning the licensure of pharmacies in each State from which it, and in each State to which it, delivers, distributes, or dispenses or offers to deliver, distribute, or dispense controlled substances by means of the Internet, pursuant to applicable licensure requirements, as determined by each such State.

(c) INTERNET PHARMACY SITE DISCLOSURE INFORMATION.—Each online pharmacy shall post in a visible and clear manner on the homepage of each Internet site it operates, or on a page directly linked thereto in which the hyperlink is also visible and clear on the homepage, the following information for each pharmacy that delivers, distributes, or dispenses controlled substances pursuant to orders made on, through, or on behalf of, that website:

(1) The name and address of the pharmacy as it appears on the pharmacy's Drug Enforcement Administration certificate of registration.

(2) The pharmacy's telephone number and email address.

(3) The name, professional degree, and States of licensure of the pharmacist-in-charge, and a telephone number at which the pharmacist-in-charge can be contacted.

(4) A list of the States in which the pharmacy is licensed to dispense controlled substances.

(5) A certification that the pharmacy is registered under this part to deliver, distribute, or dispense by means of the Internet controlled substances.

(6) The name, address, telephone number, professional degree, and States of licensure of any practitioner who has a contractual relationship to provide medical evaluations or issue prescriptions for controlled substances, through referrals from the website or at the request of the owner or operator of the website, or any employee or agent thereof.

(7) The following statement, unless revised by the Attorney General by regulation: "This online pharmacy will only dispense a controlled substance to a person who has a valid prescription issued for a legitimate medical purpose based upon a medical relationship with a prescribing practitioner. This includes at least one prior in-person medical evaluation or medical evaluation via telemedicine in accordance with applicable requirements of section 309.".

(d) NOTIFICATION.—

(1) IN GENERAL.—Thirty days prior to offering a controlled substance for sale, delivery, distribution, or dispensing, the online pharmacy shall notify the Attorney General, in such form and manner as the Attorney General shall determine, and the State boards of pharmacy in any States in which the online pharmacy offers to sell, deliver, distribute, or dispense controlled substances.

(2) CONTENTS.—The notification required under paragraph (1) shall include—

(A) the information required to be posted on the online pharmacy's Internet site under subsection (c) and shall notify the Attorney General and the applicable State boards of pharmacy, under penalty of perjury, that the information disclosed on its Internet site under subsection (c) is true and accurate;

(B) the online pharmacy's Internet site address and a certification that the online pharmacy shall notify the Attorney General of any change in the address at least 30 days in advance; and

(C) the Drug Enforcement Administration registration numbers of any pharmacies and practitioners referred to in subsection (c), as applicable.

(3) EXISTING ONLINE PHARMACIES.—An online pharmacy that is already operational as of the effective date of this section, shall notify the Attorney General and applicable State boards of pharmacy in accordance with this subsection not later than 30 days after such date.

(e) DECLARATION OF COMPLIANCE.—On and after the date on which it makes the notification under subsection (d), each online pharmacy shall display on the homepage of its Internet site, in such form as the Attorney General shall by regulation require, a declaration that it has made such notification to the Attorney General.

(f) REPORTS.—Any statement, declaration, notification, or disclosure required under this section shall be considered a report required to be kept under this part.

(g) NOTICE AND DESIGNATIONS CONCERNING INDIAN TRIBES.—

(1) IN GENERAL.—For purposes of sections 102(52) and 512(c)(6)(B), the Secretary shall notify the Attorney General, at such times and in such manner as the Secretary and the Attorney General determine appropriate, of the Indian tribes or tribal organizations with which the Secretary has contracted or compacted under the Indian Self-Determination and Education Assistance Act for the tribes or tribal organizations to provide pharmacy services.

(2) DESIGNATIONS.—

(A) IN GENERAL.—The Secretary may designate a practitioner described in subparagraph (B) as an Internet Eligible Controlled Substances Provider. Such designations shall be made only in cases where the Secretary has found that there is a legitimate need for the practitioner to be so designated because the population served by the practitioner is in a sufficiently remote location that access to medical services is limited.

(B) PRACTITIONERS.—A practitioner described in this subparagraph is a practitioner who is an employee or contractor of the Indian Health Service, or is working for an Indian tribe or tribal organization under its contract or compact under the Indian Self-Determination and Education Assistance Act with the Indian Health Service.

(h) SPECIAL REGISTRATION FOR TELEMEDICINE.—

(1) IN GENERAL.—The Attorney General may issue to a practitioner a special registration to engage in the practice of telemedicine for purposes of section 102(54)(E) if the practitioner, upon application for such special registration—

(A) demonstrates a legitimate need for the special registration; and

(B) is registered under section 303(g) in the State in which the patient will be located when receiving the telemedicine treatment, unless the practitioner—

(i) is exempted from such registration in all States under section 302(d); or

(ii) is an employee or contractor of the Department of Veterans Affairs who is acting in the scope of such employment or contract and is registered under section 303(g) in any State or is utilizing the registration of a hospital or clinic operated by the Department of Veterans Affairs registered under section 303(g).

(2) REGULATIONS.—Not later than 1 year after the date of enactment of the SUPPORT for Patients and Communities Act, in consultation with the Secretary, the Attorney General shall promulgate final regulations specifying—

(A) the limited circumstances in which a special registration under this subsection may be issued; and

(B) the procedure for obtaining a special registration under this subsection.

(3) DENIALS.—Proceedings to deny an application for registration under this subsection shall be conducted in accordance with section 304(c).

(i) REPORTING OF TELEMEDICINE BY VHA DURING MEDICAL EMERGENCY SITUATIONS.—

(1) IN GENERAL.—Any practitioner issuing a prescription for a controlled substance under the authorization to conduct telemedicine during a medical emergency situation described in section 102(54)(F) shall report to the Secretary of Veterans Affairs the authorization of that emergency prescription, in accordance with such requirements as the Secretary of Veterans Affairs shall, by regulation, establish.

(2) TO ATTORNEY GENERAL.—Not later than 30 days after the date that a prescription described in subparagraph (A) is issued, the Secretary of Veterans Affairs shall report to the Attorney General the authorization of that emergency prescription.

(j) CLARIFICATION CONCERNING PRESCRIPTION TRANSFERS.—Any transfer between pharmacies of information relating to a prescription for a controlled substance shall meet the applicable requirements under regulations promulgated by the Attorney General under this Act.

SEC. 312. [21 U.S.C. 832] SUSPICIOUS ORDERS.

(a) REPORTING.—Each registrant shall—

(1) design and operate a system to identify suspicious orders for the registrant;

(2) ensure that the system designed and operated under paragraph (1) by the registrant complies with applicable Federal and State privacy laws; and

(3) upon discovering a suspicious order or series of orders, notify the Administrator of the Drug Enforcement Administration and the Special Agent in Charge of the Division Office of the Drug Enforcement Administration for the area in which the registrant is located or conducts business.

(b) SUSPICIOUS ORDER DATABASE.—

(1) IN GENERAL.—Not later than 1 year after the date of enactment of this section, the Attorney General shall establish a centralized database for collecting reports of suspicious orders.

(2) SATISFACTION OF REPORTING REQUIREMENTS.—If a registrant reports a suspicious order to the centralized database established under paragraph (1), the registrant shall be considered to have complied with the requirement under subsection (a)(3) to notify the Administrator of the Drug Enforcement Administration and the Special Agent in Charge of the Division Office of the Drug Enforcement Administration for the area in which the registrant is located or conducts business.

(c) SHARING INFORMATION WITH THE STATES.—

(1) IN GENERAL.—The Attorney General shall prepare and make available information regarding suspicious orders in a State, including information in the database established under subsection (b)(1), to the point of contact for purposes of administrative, civil, and criminal oversight relating to the diversion of controlled substances for the State, as designated by the Governor or chief executive officer of the State.

(2) TIMING.—The Attorney General shall provide information in accordance with paragraph (1) within a reasonable period of time after obtaining the information.

(3) COORDINATION.—In establishing the process for the provision of information under this subsection, the Attorney General shall coordinate with States to ensure that the Attorney General has access to information, as permitted under State law, possessed by the States relating to prescriptions for controlled substances that will assist in enforcing Federal law.

PART D—OFFENSES AND PENALTIES

PROHIBITED ACTS A—PENALTIES

SEC. 401. [21 U.S.C. 841] (a) 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) Except as otherwise provided in section 409, 418, 419, or 420 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) 280 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) 50 grams or more of methamphetamine, its salts, isomers, and salts of its isomers or 500 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 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 $10,000,000 if the defendant is an individual or $50,000,000 if the defendant is other than an individual, or both. If any person commits such a violation after a prior conviction for a serious drug felony or serious violent felony has become final, such person shall be sentenced to a term of imprisonment of not less than 15 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 $20,000,000 if the defendant is an individual or $75,000,000 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 after 2 or more prior convictions for a serious drug felony or serious violent felony have become final, such person shall be sentenced to a term of imprisonment of not less than 25 years and fined in accordance with the preceding sentence. Notwithstanding section 3583 of title 18[41], 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) 28 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) 5 grams or more of methamphetamine, its salts, isomers, and salts of its isomers or 50 grams or more of a mixture or substance containing a detectable amount of methamphetamine, its salts, isomers, or salts of its isomers;

[41] So in law. Probably should be "title 18, United States Code". This Act does not contain a title 18.

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 $5,000,000 if the defendant is an individual or $25,000,000 if the defendant is other than an individual, or both. If any person commits such a violation after a prior conviction for a serious drug felony or serious violent felony 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 $8,000,000 if the defendant is an individual or $50,000,000 if the defendant is other than an individual, or both. Notwithstanding section 3583 of title 18[42], any sentence 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, gamma hydroxybutyric acid (including when scheduled as an approved drug product for purposes of section 3(a)(1)(B) of the Hillory J. Farias and Samantha Reid Date-Rape Drug Prohibition Act of 2000), or 1 gram of flunitrazepam, 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. Notwithstanding section 3583 of title 18[43], any sentence imposing

[42] So in law. Probably should be "title 18, United States Code". This Act does not contain a title 18.

[43] So in law. Probably should be "title 18, United States Code". This Act does not contain a title 18.

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, 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 State Code, or $500,000 if the defendant is an individual or $2,000,000 if the defendant is other than an individual, or both. Notwithstanding section 3583 of title 18[43], any sentence imposing a term of imprisonment under this paragraph shall, in the absence of such a prior conviction, impose a special parole term of at least 2 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 4 years in addition to such term of imprisonment.

(E)(i) Except as provided in subparagraphs (C) and (D), in the case of any controlled substance in schedule III, such person shall be sentenced to a term of imprisonment of not more than 10 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 more than 15 years, a fine not to exceed the greater of that authorized in accordance with the provisions of title 18, United States Code, or $500,000 if the defendant is an individual or $2,500,000 if the defendant is other than an individual, or both.

(ii) 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 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 more than 30 years, a fine not to exceed the greater of twice 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.

(iii) Any sentence imposing a term of imprisonment under this subparagraph 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 term of supervised release 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 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 the 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 term of supervised release 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 1 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 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 4 years, a fine not to exceed 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. Any sentence imposing a term of imprisonment under this paragraph may, if there was a prior conviction, impose a term of supervised release of not more than 1 year, in addition to such term of imprisonment.

(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 and section 3607 of title 18, United States Code.

(5) Any person who violates subsection (a) of this section by cultivating or manufacturing 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.

(7) PENALTIES FOR DISTRIBUTION.—

(A) IN GENERAL.—Whoever, with intent to commit a crime of violence, as defined in section 16 of title 18, United States Code (including rape), against an individual, violates subsection (a) by distributing a controlled substance or controlled substance analogue to that individual without that individual's knowledge, shall be imprisoned not more than 20 years and fined in accordance with title 18, United States Code.

(B) DEFINITION.—For purposes of this paragraph, the term "without that individual's knowledge" means that the individual is unaware that a substance with the ability to alter that individual's ability to appraise conduct or to decline participation in or communicate unwillingness to participate in conduct is administered to the individual.

(c) 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, 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 20 years in the case of a violation of paragraph (1) or (2) involving a list I chemical or not more than 10 years in the case of a violation of this subsection other than a violation of paragraph (1) or (2) involving a list I chemical, or both.

(d)(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 or fined under title 18, United States Code, or both.

(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 or fined under title 18, United States Code, or both.

(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.

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

(f)(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) shall, except to the extent that paragraph (12), (13), or (14) of section 402(a) applies, 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 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.

(g) INTERNET SALES OF DATE RAPE DRUGS.—

(1) Whoever knowingly uses the Internet to distribute a date rape drug to any person, knowing or with reasonable cause to believe that—

(A) the drug would be used in the commission of criminal sexual conduct; or

(B) the person is not an authorized purchaser;

shall be fined under this title or imprisoned not more than 20 years, or both.

(2) As used in this subsection:

(A) The term "date rape drug" means—

(i) gamma hydroxybutyric acid (GHB) or any controlled substance analogue of GHB, including gamma butyrolactone (GBL) or 1,4–butanediol;

(ii) ketamine;

(iii) flunitrazepam; or

(iv) any substance which the Attorney General designates, pursuant to the rulemaking procedures prescribed by section 553 of title 5, United States Code, to be used in committing rape or sexual assault.

The Attorney General is authorized to remove any substance from the list of date rape drugs pursuant to the same rulemaking authority.

(B) The term "authorized purchaser" means any of the following persons, provided such person has acquired the controlled substance in accordance with this Act:

(i) A person with a valid prescription that is issued for a legitimate medical purpose in the usual course of professional practice that is based upon a qualifying medical relationship by a practitioner registered by the Attorney General. A "qualifying medical relationship" means a medical relationship that exists when the practitioner has conducted at least 1 medical evaluation with the authorized purchaser in the physical presence of the practitioner, without regard to

whether portions of the evaluation are conducted by other heath professionals. The preceding sentence shall not be construed to imply that 1 medical evaluation demonstrates that a prescription has been issued for a legitimate medical purpose within the usual course of professional practice.

(ii) Any practitioner or other registrant who is otherwise authorized by their registration to dispense, procure, purchase, manufacture, transfer, distribute, import, or export the substance under this Act.

(iii) A person or entity providing documentation that establishes the name, address, and business of the person or entity and which provides a legitimate purpose for using any "date rape drug" for which a prescription is not required.

(3) The Attorney General is authorized to promulgate regulations for record-keeping and reporting by persons handling 1,4–butanediol in order to implement and enforce the provisions of this section. Any record or report required by such regulations shall be considered a record or report required under this Act.

(h) OFFENSES INVOLVING DISPENSING OF CONTROLLED SUBSTANCES BY MEANS OF THE INTERNET.—

(1) IN GENERAL.—It shall be unlawful for any person to knowingly or intentionally—

(A) deliver, distribute, or dispense a controlled substance by means of the Internet, except as authorized by this title; or

(B) aid or abet (as such terms are used in section 2 of title 18, United States Code) any activity described in subparagraph (A) that is not authorized by this title.

(2) EXAMPLES.—Examples of activities that violate paragraph (1) include, but are not limited to, knowingly or intentionally—

(A) delivering, distributing, or dispensing a controlled substance by means of the Internet by an online pharmacy that is not validly registered with a modification authorizing such activity as required by section 303(g) (unless exempt from such registration);

(B) writing a prescription for a controlled substance for the purpose of delivery, distribution, or dispensation by means of the Internet in violation of section 309(e);

(C) serving as an agent, intermediary, or other entity that causes the Internet to be used to bring together a buyer and seller to engage in the dispensing of a controlled substance in a manner not authorized by sections 303(g) or 309(e);

(D) offering to fill a prescription for a controlled substance based solely on a consumer's completion of an online medical questionnaire; and

(E) making a material false, fictitious, or fraudulent statement or representation in a notification or declaration under subsection (d) or (e), respectively, of section 311.

(3) INAPPLICABILITY.—

(A) This subsection does not apply to—

(i) the delivery, distribution, or dispensation of controlled substances by nonpractitioners to the extent authorized by their registration under this title;

(ii) the placement on the Internet of material that merely advocates the use of a controlled substance or includes pricing information without attempting to propose or facilitate an actual transaction involving a controlled substance; or

(iii) except as provided in subparagraph (B), any activity that is limited to—

(I) the provision of a telecommunications service, or of an Internet access service or Internet information location tool (as those terms are defined in section 231 of the Communications Act of 1934); or

(II) the transmission, storage, retrieval, hosting, formatting, or translation (or any combination thereof) of a communication, without selection or alteration of the content of the communication, except that deletion of a particular communication or material made by another person in a manner consistent with section 230(c) of the Communications Act of 1934 shall not constitute such selection or alteration of the content of the communication.

(B) The exceptions under subclauses (I) and (II) of subparagraph (A)(iii) shall not apply to a person acting in concert with a person who violates paragraph (1).

(4) KNOWING OR INTENTIONAL VIOLATION.—Any person who knowingly or intentionally violates this subsection shall be sentenced in accordance with subsection (b).

PROHIBITED ACTS B—PENALTIES

SEC. 402. [21 U.S.C. 842] (a) It shall be unlawful for any person—

(1) who is subject to the requirements of part C to distribute or dispense a controlled substance in violation of section 309;

(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;

(4) to remove, alter, or obliterate a symbol or label required by section 305 of this title;

(5) to refuse or negligently 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 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);

(10) negligently to fail to keep a record or make a report under section 310 or negligently to fail to self-certify as required under section 310;

(11) to distribute a laboratory supply to a person who uses, or attempts to use, that laboratory supply to manufacture a controlled substance or a listed chemical, in violation of this title or title III, with reckless disregard for the illegal uses to which such a laboratory supply will be put;

(12) who is a regulated seller, or a distributor required to submit reports under subsection (b)(3) of section 310—

(A) to sell at retail a scheduled listed chemical product in violation of paragraph (1) of subsection (d) of such section, knowing at the time of the transaction involved (independent of consulting the logbook under subsection (e)(1)(A)(iii) of such section) that the transaction is a violation; or

(B) to knowingly or recklessly sell at retail such a product in violation of paragraph (2) of such subsection (d);

(13) who is a regulated seller to knowingly or recklessly sell at retail a scheduled listed chemical product in violation of subsection (e) of such section;

(14) who is a regulated seller or an employee or agent of such seller to disclose, in violation of regulations under subparagraph (C) of section 310(e)(1), information in logbooks under subparagraph (A)(iii) of such section, or to refuse to provide such a logbook to Federal, State, or local law enforcement authorities;

(15) to distribute a scheduled listed chemical product to a regulated seller, or to a regulated person referred to in section 310(b)(3)(B), unless such regulated seller or regulated person is, at the time of such distribution, currently registered with the Drug Enforcement Administration, or on the list of persons referred to under section 310(e)(1)(B)(v);

(16) to violate subsection (e) of section 825 of this title; or

(17) in the case of a registered manufacturer or distributor of opioids, to fail to review the most recent information, directly related to the customers of the manufacturer or distributor, made available by the Attorney General in accordance with section 307(f).

As used in paragraph (11), the term "laboratory supply" means a listed chemical or any chemical, substance, or item on a special surveillance list published by the Attorney General, which contains chemicals, products, materials, or equipment used in the manufacture of controlled substances and listed chemicals. For purposes of paragraph (11), there is a rebuttable presumption of reckless disregard at trial if the Attorney General notifies a firm in writing that a laboratory supply sold by the firm, or any other person or firm, has been used by a customer of the notified firm, or distributed further by that customer, for the unlawful production of controlled substances or listed chemicals a firm distributes and 2 weeks or more after the notification the notified firm distributes a laboratory supply to the customer. For purposes of paragraph (15), if the distributor is temporarily unable to access the list of persons referred to under section 310(e)(1)(B)(v), the distributor may rely on a written, faxed, or electronic copy of a certificate of self-certification submitted by the regulated seller or regulated person, provided the distributor confirms within 7 business days of the distribution that such regulated seller or regulated person is on the list referred to under section 310(e)(1)(B)(v).

(b) It shall be unlawful for any person who is a registrant to manufacture a controlled substance in schedule I or II, or ephedrine, pseudoephedrine, or phenylpropanolamine or any of the salts, optical isomers, or salts of optical isomers of such chemical, which is—

(1) not expressly authorized by his registration and by a quota assigned to him pursuant to section 306; or

(2) in excess of a quota assigned to him pursuant to section 306.

(c)(1)(A) Except as provided in subparagraph (B), (C), or (D) of this paragraph and 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 of the United States Code to enforce this paragraph.

(B)(i) Except as provided in clause (ii), in the case of a violation of paragraph (5), (10), or (17) of subsection (a), the civil penalty shall not exceed $10,000.

(ii) In the case of a violation described in clause (i) committed by a registered manufacturer or distributor of opioids and related to the reporting of suspicious orders for opioids, failing to maintain effective controls against diversion of opioids, or failing to review the most recent information made available by the Attorney General in accordance with section 307(f), the penalty shall not exceed $100,000.

(C) In the case of a violation of paragraph (16) of subsection (a) of this section by an importer, exporter, manufacturer, or distributor (other than as provided in subparagraph (D)), up to $500,000 per violation. For purposes of this subparagraph, a viola-

tion is defined as each instance of importation, exportation, manufacturing, distribution, or possession with intent to manufacture or distribute, in violation of paragraph (16) of subsection (a).

(D) In the case of a distribution, dispensing, or possession with intent to distribute or dispense in violation of paragraph (16) of subsection (a) of this section at the retail level, up to $1000 per violation. For purposes of this paragraph, the term "at the retail level" refers to products sold, or held for sale, directly to the consumer for personal use. Each package, container or other separate unit containing an anabolic steroid that is distributed, dispensed, or possessed with intent to distribute or dispense at the retail level in violation of such paragraph (16) of subsection (a) shall be considered a separate violation.

(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) or (D) of this paragraph, be sentenced to imprisonment of not more than one year or a fine under title 18, United States Code, 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 under title 18, United States Code, or both.

(C) In addition to the penalties set forth elsewhere in this title or title III, any business that violates paragraph (11) of subsection (a) shall, with respect to the first such violation, be subject to a civil penalty of not more than $250,000, but shall not be subject to criminal penalties under this section, and shall, for any succeeding violation, be subject to a civil fine of not more than $250,000 or double the last previously imposed penalty, whichever is greater.

(D) In the case of a violation described in subparagraph (A) that was a violation of paragraph (5), (10), or (17) of subsection (a) committed by a registered manufacturer or distributor of opioids that relates to the reporting of suspicious orders for opioids, failing to maintain effective controls against diversion of opioids, or failing to review the most recent information made available by the Attorney General in accordance with section 307(f), the criminal fine under title 18, United States Code, shall not exceed $500,000.

(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.

(4)(A) If a regulated seller, or a distributor required to submit reports under section 310(b)(3), violates paragraph (12) of subsection (a) of this section, or if a regulated seller violates paragraph (13) of such subsection, the Attorney General may by order prohibit such seller or distributor (as the case may be) from selling any

scheduled listed chemical product. Any sale of such a product in violation of such an order is subject to the same penalties as apply under paragraph (2).

(B) An order under subparagraph (A) may be imposed only through the same procedures as apply under section 304(c) for an order to show cause.

PROHIBITED ACTS C—PENALTIES

SEC. 403. [21 U.S.C. 843] (a) 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;

(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 a listed chemical and the person is required to present identification under section 310(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;

(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 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) 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)(1)[44] 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.

(2)(A) It shall be unlawful for any person to knowingly or intentionally use the Internet, or cause the Internet to be used, to advertise the sale of, or to offer to sell, distribute, or dispense, a controlled substance where such sale, distribution, or dispensing is not authorized by this title or by the Controlled Substances Import and Export Act.

(B) Examples of activities that violate subparagraph (A) include, but are not limited to, knowingly or intentionally causing the placement on the Internet of an advertisement that refers to or directs prospective buyers to Internet sellers of controlled substances who are not registered with a modification under section 303(g).

(C) Subparagraph (A) does not apply to material that either—

(i) merely advertises the distribution of controlled substances by nonpractitioners to the extent authorized by their registration under this title; or

(ii) merely advocates the use of a controlled substance or includes pricing information without attempting to facilitate an actual transaction involving a controlled substance.

(d)(1) Except as provided in paragraph (2), any person who violates this section shall be sentenced to a term of imprisonment of not more than 4 years, a fine under title 18, United States Code, 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

[44] References in subsection (c)(1) to "Schedule I" probably should be "schedule I".

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 under title 18, United States Code, or both.

(2) Any person who, with the intent to manufacture or to facilitate the manufacture of methamphetamine, violates paragraph (6) or (7) of subsection (a), shall be sentenced to a term of imprisonment of not more than 10 years, a fine under title 18, United States Code, or both; except that if any person commits such a violation after one or more prior convictions of that person—

(A) for a violation of paragraph (6) or (7) of subsection (a);

(B) for a felony under any other provision of this subchapter or subchapter II of this chapter;[45] or

(C) under any other law of the United States or any State relating to controlled substances or listed chemicals,

has become final, such person shall be sentenced to a term of imprisonment of not more than 20 years, a fine under title 18, United States Code, or both.

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

(f) INJUNCTIONS.—(1) In addition to any penalty provided in this section, the Attorney General is authorized to commence a civil action for appropriate declaratory or injunctive relief relating to violations of this section, section 402, or 416[46].

(2) Any action under this subsection may be brought in the district court of the United States for the district in which the defendant is located or resides or is doing business.

(3) Any order or judgment issued by the court pursuant to this subsection shall be tailored to restrain violations of this section or section 402.

(4) The court shall proceed as soon as practicable to the hearing and determination of such an action. An action under this subsection is governed by the Federal Rules of Civil Procedure except that, if an indictment has been returned against the respondent, discovery is governed by the Federal Rules of Criminal Procedure.

PENALTY FOR SIMPLE POSSESSION

SEC. 404. [21 U.S.C. 844] (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

[45] So in law. See section 203(a) of Public Law 104–237 (110 Stat. 3102). The reference to "this subchapter or subchapter II of this chapter" probably should be a reference to "this title or title III". The Controlled Substances Act does not contain any chapters or subchapters. (The Controlled Substances Act is title II of Public Law 91–513, and the Controlled Substances Import and Export Act is title III of such Public Law.)

[46] So in law. Probably should be "section 416". See section 608(d) of Public Law 108–21 (117 Stat. 691).

this title or title III. It shall be unlawful for any person knowingly or intentionally to possess any list I chemical obtained pursuant to or under authority of a registration issued to that person under section 303 of this title or section 1008 of title III if that registration has been revoked or suspended, if that registration has expired, or if the registrant has ceased to do business in the manner contemplated by his registration. It shall be unlawful for any person to knowingly or intentionally purchase at retail during a 30 day period more than 9 grams of ephedrine base, pseudoephedrine base, or phenylpropanolamine base in a scheduled listed chemical product, except that, of such 9 grams, not more than 7.5 grams may be imported by means of shipping through any private or commercial carrier or the Postal Service. Any person who violates this subsection shall be sentenced to a term of imprisonment of not more than 1 year, and 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, narcotic, or chemical 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, narcotic, or chemical 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 any penalty provided in this subsection, any person convicted under this subsection for the possession of flunitrazepam shall be imprisoned for not more than 3 years, shall be fined as otherwise provided in this section, or both. 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.

(c)[47] As used in this section, the term "drug, narcotic, or chemical 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.

SEC. 405. [21 U.S.C. 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) in violation of section 404 in an amount that, as specified by regulation of

[47] So in law. Section 404 does not contain a subsection (b). See sections 219 and 235 of Public Law 98–473 (98 Stat. 2027, 2031) and section 1052 of Public Law 99–570 (100 Stat. 3207–8).

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 [48] 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.

ATTEMPT AND CONSPIRACY

SEC. 406. [21 U.S.C. 846] 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.

ADDITIONAL PENALTIES

SEC. 407. [21 U.S.C. 847] 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.

CONTINUING CRIMINAL ENTERPRISE

SEC. 408. [21 U.S.C. 848] (a) 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; except that if any person engages in such activity after one or more prior convic-

[48] So in law. See section 6486(i) of Public Law 100–690 (102 Stat. 4384). Probably should be "section". (Section 6486(i) of such Public Law was transferred to this Act and redesignated as section 405 by section 1002(g)(1) of Public Law 101–647 (104 Stat. 4828).)

tions 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.

(b) 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, 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.

(c) 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) 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.

Death Penalty

(e)(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) 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; and

(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.

Appeal in Capital Cases; Counsel for Financially Unable Defendants

(q)[49]

(s)[50] SPECIAL PROVISION FOR METHAMPHETAMINE.—For the purposes of subsection (b), in the case of continuing criminal enterprise involving methamphetamine or its salts, isomers, or salts of isomers, paragraph (2)(A) shall be applied by substituting "200" for "300", and paragraph (2)(B) shall be applied by substituting "$5,000,000" for "$10 million dollars".

TRANSPORTATION SAFETY OFFENSES

SEC. 409. [21 U.S.C. 849] (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 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)[51]) subject to—

(1) twice the maximum punishment authorized by section 401(b); and

(2) twice any term of supervised release authorized by section 401(b) for a first offense.

[49] So in law. See amendments made by sections 221(4) and 222(c) of Public Law 109–177 (120 Stat. 231).

[50] So in law. There are no subsections (f) through (q) and (r) in section 408.

[51] So in law. Probably should be "subsection (c)".

(c) SUBSEQUENT OFFENSE.—A person who violates section 401(a)(1) or section 416 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)[52] have become final is subject to—

(1) 3 times the maximum punishment authorized by section 401(b); and

(2) 3 times any term of supervised release authorized by section 401(b) for a first offense.

INFORMATION FOR SENTENCING

SEC. 410. [21 U.S.C. 850] Except as otherwise provided in this title or section 303(a) of the Public Health Service Act[53], 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.

PROCEEDINGS TO ESTABLISH PRIOR CONVICTIONS

SEC. 411. [21 U.S.C. 851] (a)(1) No person who stands convicted of an offense under this part 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) 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.

(c)(1) If the person denies any allegation of the information of prior conviction, or claims that any conviction alleged is invalid, he shall file a written response to the information. A copy of the response shall be served upon the United States attorney. The court

[52] So in law. Probably should be "subsection (b)".

[53] Section 303 of the Public Health Service Act was repealed by section 3201(b)(1) of Public Law 106–310 (114 Stat. 1190).

shall hold a hearing to determine any issues raised by the response which would except the person from increased punishment. The failure of the United States attorney to include in the information the complete criminal record of the person or any facts in addition to the convictions to be relied upon shall not constitute grounds for invalidating the notice given in the information required by subsection (a)(1). The hearing shall be before the court without a jury and either party may introduce evidence. Except as otherwise provided in paragraph (2) of this subsection, the United States attorney shall have the burden of proof beyond a reasonable doubt on any issue of fact. At the request of either party, the court shall enter findings of fact and conclusions of law.

(2) A person claiming that a conviction alleged in the information was obtained in violation of the Constitution of the United States shall set forth his claim, and the factual basis therefor, with particularity in his response to the information. The person shall have the burden of proof by a preponderance of the evidence on any issue of fact raised by the response. Any challenge to a prior conviction, not raised by response to the information before an increased sentence is imposed in reliance thereon, shall be waived unless good cause be shown for failure to make a timely challenge.

(d)(1) If the person files no response to the information, or if the court determines, after hearing, that the person is subject to increased punishment by reason of prior convictions, the court shall proceed to impose sentence upon him as provided by this part.

(2) If the court determines that the person has not been convicted as alleged in the information, that a conviction alleged in the information is invalid, or that the person is otherwise not subject to an increased sentence as a matter of law, the court shall, at the request of the United States attorney, postpone sentence to allow an appeal from that determination. If no such request is made, the court shall impose sentence as provided by this part. The person may appeal from an order postponing sentence as if sentence had been pronounced and a final judgment of conviction entered.

(e) No person who stands convicted of an offense under this part may challenge the validity of any prior conviction alleged under this section which occurred more than five years before the date of the information alleging such prior conviction.

APPLICATION OF TREATIES AND OTHER INTERNATIONAL AGREEMENTS

SEC. 412. [21 U.S.C. 852] Nothing in the Single Convention on Narcotic Drugs, the Convention on Psychotropic Substances, or other treaties or international agreements shall be construed to limit the provision of treatment, education, or rehabilitation as alternatives to conviction or criminal penalty for offenses involving any drug or other substance subject to control under any such treaty or agreement.

CRIMINAL FORFEITURES

PROPERTY SUBJECT TO CRIMINAL FORFEITURE

SEC. 413. [21 U.S.C. 853] (a) Any person convicted of a violation of this title or title III punishable by imprisonment for more

than one year shall forfeit to the United States, irrespective of any provision of State law—

(1) any property constituting, or derived from, any proceeds the person obtained, directly or indirectly, as the result of such violation;

(2) any of the person's property used, or intended to be used, in any manner or part, to commit, or to facilitate the commission of, such violation; and

(3) in the case of a person convicted of engaging in a continuing criminal enterprise in violation of section 408 of this title (21 U.S.C. 848), the person shall forfeit, in addition to any property described in paragraph (1) or (2), any of his interest in, claims against, and property or contractual rights affording a source of control over, the continuing criminal enterprise.

The court, in imposing sentence on such person, shall order, in addition to any other sentence imposed pursuant to this title or title III, that the person forfeit to the United States all property described in this subsection. In lieu of a fine otherwise authorized by this part, a defendant who derives profits or other proceeds from an offense may be fined not more than twice the gross profits or other proceeds.

MEANING OF TERM "PROPERTY"

(b) Property subject to criminal forfeiture under this section includes—

(1) real property, including things growing on, affixed to, and found in land; and

(2) tangible and intangible personal property, including rights, privileges, interests, claims, and securities.

THIRD PARTY TRANSFERS

(c) All right, title, and interest in property described in subsection (a) vests in the United States upon the commission of the act giving rise to forfeiture under this section. Any such property that is subsequently transferred to a person other than the defendant may be the subject of a special verdict of forfeiture and thereafter shall be ordered forfeited to the United States, unless the transferee establishes in a hearing pursuant to subsection (n) that he is a bona fide purchaser for value of such property who at the time of purchase was reasonably without cause to believe that the property was subject to forfeiture under this section.

REBUTTABLE PRESUMPTION

(d) There is a rebuttable presumption at trial that any property of a person convicted of a felony under this title or title III is subject to forfeiture under this section if the United States establishes by a preponderance of the evidence that—

(1) such property was acquired by such person during the period of the violation of this title or title III or within a reasonable time after such period; and

(2) there was no likely source for such property other than the violation of this title or title III.

PROTECTIVE ORDERS

(e)(1) Upon application of the United States, the court may enter a restraining order or injunction, require the execution of a satisfactory performance bond, or take any other action to preserve the availability of property described in subsection (a) for forfeiture under this section—

(A) upon the filing of an indictment or information charging a violation of this title or title III for which criminal forfeiture may be ordered under this section and alleging that the property with respect to which the order is sought would, in the event of conviction, be subject to forfeiture under this section; or

(B) prior to the filing of such an indictment or information, if, after notice to persons appearing to have an interest in the property and opportunity for a hearing, the court determines that—

(i) there is a substantial probability that the United States will prevail on the issue of forfeiture and that failure to enter the order will result in the property being destroyed, removed from the jurisdiction of the court, or otherwise made unavailable for forfeiture; and

(ii) the need to preserve the availability of the property through the entry of the requested order outweighs the hardship on any party against whom the order is to be entered:

Provided, however, That an order entered pursuant to subparagraph (B) shall be effective for not more than ninety days, unless extended by the court for good cause shown or unless an indictment or information described in subparagraph (A) has been filed.

(2) A temporary restraining order under this subsection may be entered upon application of the United States without notice or opportunity for a hearing when an information or indictment has not yet been filed with respect to the property, if the United States demonstrates that there is probable cause to believe that the property with respect to which the order is sought would, in the event of conviction, be subject to forfeiture under this section and that provision of notice will jeopardize the availability of the property for forfeiture. Such a temporary order shall expire not more than fourteen days after the date on which it is entered, unless extended for good cause shown or unless the party against whom it is entered consents to an extension for a longer period. A hearing requested concerning an order entered under this paragraph shall be held at the earliest possible time and prior to the expiration of the temporary order.

(3) The court may receive and consider, at a hearing held pursuant to this subsection, evidence and information that would be inadmissible under the Federal Rules of Evidence.

(4)[54] ORDER TO REPATRIATE AND DEPOSIT.—

(A) IN GENERAL.—Pursuant to its authority to enter a pretrial restraining order under this section, the court may order a defendant to repatriate any property that may be

[54] Indentation is so in law. See section 319(d)(2) of Public Law 107–56 (115 Stat. 314).

seized and forfeited, and to deposit that property pending trial in the registry of the court, or with the United States Marshals Service or the Secretary of the Treasury, in an interest-bearing account, if appropriate.

(B) FAILURE TO COMPLY.—Failure to comply with an order under this subsection, or an order to repatriate property under subsection (p), shall be punishable as a civil or criminal contempt of court, and may also result in an enhancement of the sentence of the defendant under the obstruction of justice provision of the Federal Sentencing Guidelines.

WARRANT OF SEIZURE

(f) The Government may request the issuance of a warrant authorizing the seizure of property subject to forfeiture under this section in the same manner as provided for a search warrant. If the court determines that there is probable cause to believe that the property to be seized would, in the event of conviction, be subject to forfeiture and that an order under subsection (e) may not be sufficient to assure the availability of the property for forfeiture, the court shall issue a warrant authorizing the seizure of such property.

EXECUTION

(g) Upon entry of an order of forfeiture under this section, the court shall authorize the Attorney General to seize all property ordered forfeited upon such terms and conditions as the court shall deem proper. Following entry of an order declaring the property forfeited, the court may, upon application of the United States, enter such appropriate restraining orders or injunctions, require the execution of satisfactory performance bonds, appoint receivers, conservators, appraisers, accountants, or trustees, or take any other action to protect the interest of the United States in the property ordered forfeited. Any income accuring to or derived from property ordered forfeited under this section may be used to offset ordinary and necessary expenses to the property which are required by law, or which are necessary to protect the interests of the United States or third parties.

DISPOSITION OF PROPERTY

(h) Following the seizure of property ordered forfeited under this section, the Attorney General shall direct the disposition of the property by sale of any other any other commercially feasible means, making due provision for the rights of any innocent persons. Any property right or interest not exercisable by, or transferable for value to, the United States shall expire and shall not revert to the defendant, nor shall the defendant or any person acting in concert with him or on his behalf be eligible to purchase forfeited property at any sale held by the United States. Upon application of a person, other than the defendant or a person acting in concert with him or on his behalf, the court may restrain or stay the sale or disposition of the property pending the conclusion of any appeal of the criminal case giving rise to the forefeiture, if the ap-

plicant demonstrates that proceeding with the sale or disposition of the property will result in irreparable injury, harm, or loss to him.

AUTHORITY OF THE ATTORNEY GENERAL

(i) With respect to property ordered forfeited under this section, the Attorney General is authorized to—

(1) grant petitions for mitigation or remission of forfeiture, restore forfeited property to victims of a violation of this title, or take any other action to protect the rights of innocent persons which is in the interest of justice and which is not inconsistent with the provisions of this section;

(2) compromise claims arising under this section;

(3) award compensation to persons providing information resulting in a forfeiture under this section;

(4) direct the disposition by the United States, in accordance with the provisions of section 511(e) of this title (21 U.S.C. 881(e)), of all property ordered forfeited under this section by public sale or any other commerically feasible means, making due provision for the rights of innocent persons; and

(5) take appropriate measures necessary to safeguard and maintain property ordered forfeited under this section pending its disposition.

APPLICABILITY OF CIVIL FORFEITURE PROVISIONS

(j) Except to the extent that they are inconsistent with the provisions of this section, the provisions of section 511(d) of this title (21 U.S.C. 881(d)) shall apply to a criminal forfeiture under this section.

BAR ON INTERVENTION

(k) Except as provided in subsection (n), no party claiming an interest in property subject to forfeiture under this section may—

(1) intervene in a trial or appeal of a criminal case involving the forfeiture of such property under this section; or

(2) commence an action at law or equity against the United States concerning the validity of his alleged interest in the property subsequent to the filing of an indictment or information alleging that the property in subject to forfeiture under this section.

JURISDICTION TO ENTER ORDERS

(l) The district courts of the United States shall have jurisdiction to enter orders as provided in this section without regard to the location of any property which may be subject to forfeiture under this section or which has been ordered forfeited under this section.

DEPOSITIONS

(m) In order to facilitate the identification and location of property declared forfeited and to facilitate the disposition of petitions for remission or mitigation of forfeiture, after the entry of an order declaring property forfeited to the United States, the court may, upon application of the United States, order that the testimony of

any witness relating to the property forfeited be taken by deposition and that any designated book, paper, document, record, recording, or other material not privileged be produced at the same time any place, in the same manner as provided for the taking of depositions under Rule 15 of the Federal Rules of Criminal Procedure.

THIRD PARTY INTERESTS

(n)(1) Following the entry of an order of forfeiture under this section, the United States shall publish notice of the order and of its intent to dispose of the property in such manner as the Attorney General may direct. The Government may also, to the extent practicable, provide direct written notice to any person known to have alleged an interest in the property that is the subject of the order of forfeiture as a substitute for published notice as to those persons so notified.

(2) Any person, other than the defendant, asserting a legal interest in property which has been ordered forfeited to the United States pursuant to this section may, within thirty days of the final publication of notice or his receipt of notice under paragraph (1), whichever is earlier, petition the court for a hearing to adjudicate the validity of his alleged interest in the property. The hearing shall be held before the court alone, without a jury.

(3) The petition shall be signed by the petitioner under penalty of perjury and shall set forth the nature and extent of the petitioner's right, title, or interest in the property, the time and circumstances of the petitioner's acquisition of the right, title, or interest in the property, and additional facts supporting the petitioner's claim, and the relief sought.

(4) The hearing on the petition shall, to the extent practicable and consistent with the interests of justice, be held within thirty days of the filing of the petition. The court may consolidate the hearing on the petition with a hearing on any other petition filed by a person other than the defendant under this subsection.

(5) At the hearing, the petitioner may testify and present evidence and witnesses on his own behalf, and cross-examine witnesses who appear at the hearing. The United States may present evidence and witnesses in rebuttal and in defense of this claim to the property and cross-examine witnesses who appear at the hearing, the court shall consider the relevant portions of the record of the criminal case which resulted in the order of forfeiture.

(6) If, after the hearing, the court determines that the petitioner has established by a preponderance of the evidence that—

(A) the petitioner has a legal right, title, or interest in the property, and such right, title, or interest renders the order of forfeiture invalid in whole or in part because the right, title, or interest was vested in the petitioner rather than the defendant or was superior to any right, title, or interest of the defendant at the time of the commission of the acts which gave rise to the forfeiture of the property under the section; or

(B) the petitioner is a bona fide purchaser for value of the right, title, or interest in the property and was at the time of purchase reasonably without cause to believe that the property was subject to forfeiture under this section;

the court shall amend the order of forfeiture in accordance with its determination.

(7) Following the court's disposition of all petitions filed under this subsection, or if no such petitions are filed following the expiration of the period provided in paragraph (2) for the filing of such petitions, the United States shall have clear title to property that is the subject of the order of forfeiture and may warrant good title to any subsequent purchaser or transferee.

(o) The provisions of this section shall be liberally construed to effectuate its remedial purposes.

(p) FORFEITURE OF SUBSTITUTE PROPERTY.—

(1) IN GENERAL.—Paragraph (2) of this subsection shall apply, if any property described in subsection (a), as a result of any act or omission of the defendant—

(A) cannot be located upon the exercise of due diligence;

(B) has been transferred or sold to, or deposited with, a third party;

(C) has been placed beyond the jurisdiction of the court;

(D) has been substantially diminished in value; or

(E) has been commingled with other property which cannot be divided without difficulty.

(2) SUBSTITUTE PROPERTY.—In any case described in any of subparagraphs (A) through (E) of paragraph (1), the court shall order the forfeiture of any other property of the defendant, up to the value of any property described in subparagraphs (A) through (E) of paragraph (1), as applicable.

(3) RETURN OF PROPERTY TO JURISDICTION.—In the case of property described in paragraph (1)(C), the court may, in addition to any other action authorized by this subsection, order the defendant to return the property to the jurisdiction of the court so that the property may be seized and forfeited.

(q) The court, when sentencing a defendant convicted of an offense under this title or title III involving the manufacture, the possession, or the possession with intent to distribute, of amphetamine or methamphetamine, shall—

(1) order restitution as provided in sections 3612 and 3664 of title 18, United States Code;

(2) order the defendant to reimburse the United States, the State or local government concerned, or both the United States and the State or local government concerned for the costs incurred by the United States or the State or local government concerned, as the case may be, for the cleanup associated with the manufacture of amphetamine or methamphetamine by the defendant, or on premises or in property that the defendant owns, resides, or does business in; and

(3) order restitution to any person injured as a result of the offense as provided in section 3663A of title 18, United States Code.

INVESTMENT OF ILLICIT DRUG PROFITS

SEC. 414. [21 U.S.C. 854] (a) It shall be unlawful for any person who has received any income derived, directly or indirectly, from a violation of this title of title III punishable by imprisonment for more than one year in which such person has participated as a principal within the meaning of section 2 of title 18, United States Code, to use or invest, directly or indirectly, any part of such income, or the proceeds of such income, in acquistion of any interest in, or the establishment or operation of, any enterprise which is engaged in, or the activities of which affect interstate or foreign commerce. A purchase of securities on the open market for purposes of investment, and without the intention of controlling or participating in the control of the issuer, or of assisting another to do so, shall not be unlawful under this section if the securities of the issuer held by the purchaser, the members of his immediate family, and his or their accomplices in any violation of this title or title III after such purchases do not amount in the aggregate to 1 per centum of the outstanding securities of any one class, and do not confer, either in law or in fact, the power to elect one or more directors of this issuer.

(b) Whoever violates this section shall be fined not more than $50,000 or imprisoned not more than ten years, or both.

(c) As used in this section, the term "enterprise" includes any individual, partnership, corporation, association, or other legal entity, and any union or group of individuals associated in fact although not a legal entity.

(d) The provisions of this section shall be liberally construed to effectuate its remedial purposes.

ALTERNATIVE FINE

SEC. 415. [21 U.S.C. 855] In lieu of a fine otherwise authorized by this part, a defendant who derives profits or other proceeds from an offense may be fined not more than twice the gross profits or other proceeds.

SEC. 416. [21 U.S.C. 856] MAINTAINING DRUG-INVOLVED PREMISES.

(a) Except as authorized by this title, it shall be unlawful to—

(1) knowingly open, lease, rent, use, or maintain any place, whether permanently or temporarily, for the purpose of manufacturing, distributing, or using any controlled substance;

(2) manage or control any place, whether permanently or temporarily, either as an owner, lessee, agent, employee, occupant, or mortgagee, and knowingly and intentionally rent, lease, profit from, or make available for use, with or without compensation, the place for the purpose of unlawfully manufacturing, storing, distributing, or using a controlled substance.

(b) Any person who violates subsection (a) of this section shall be sentenced to a term of imprisonment of not more than 20 years or a fine of not more than $500,000, or both, or a fine of $2,000,000 for a person other than an individual.

(c) A violation of subsection (a) shall be considered an offense against property for purposes of section 3663A(c)(1)(A)(ii) of title 18, United States Code.

(d)(1) Any person who violates subsection (a) shall be subject to a civil penalty of not more than the greater of—

(A) $250,000; or

(B) 2 times the gross receipts, either known or estimated, that were derived from each violation that is attributable to the person.

(2) If a civil penalty is calculated under paragraph (1)(B), and there is more than 1 defendant, the court may apportion the penalty between multiple violators, but each violator shall be jointly and severally liable for the civil penalty under this subsection.

(e) Any person who violates subsection (a) shall be subject to declaratory and injunctive remedies as set forth in section 403(f).

ENDANGERING HUMAN LIFE WHILE ILLEGALLY MANUFACTURING A CONTROLLED SUBSTANCE

SEC. 417. [21 U.S.C. 858] Whoever, while manufacturing a controlled substance in violation of this title, or attempting to do so, or transporting or causing to be transported materials, including chemicals, to do so, creates a substantial risk of harm to human life shall be fined in accordance with title 18, United States Code, or imprisoned not more than 10 years, or both.

DISTRIBUTION TO PERSONS UNDER AGE TWENTY-ONE

SEC. 418. [21 U.S.C. 859] (a) Except as provided in section 419, any person at least eighteen years of age who violates section 401(a)(1) by distributing a controlled substance to a person under twenty-one years of age is (except as provided in subsection (b)) subject to (1) twice the maximum punishment authorized by section 401(b), and (2) at least twice any term of supervised release authorized by section 401(b), for a first offense involving the same controlled substance and schedule. Except to the extent a greater minimum sentence is otherwise provided by section 401(b), a term of imprisonment under this subsection shall be not less than one year. The mandatory minimum sentencing provisions of this subsection shall not apply to offenses involving 5 grams or less of marihuana.

(b) Except as provided in section 419, any person at least eighteen years of age who violates section 401(a)(1) by distributing a controlled substance to a person under twenty-one years of age after a prior conviction under subsection (a) of this section (or under section 303(b)(2) of the Federal Food, Drug, and Cosmetic Act as in effect prior to the effective date of section 701(b) of this Act) has become final, is subject to (1) three times the maximum punishment authorized by section 401(b), and (2) at least three times any term of supervised release authorized by section 401(b), for a second offense or subsequent offense involving the same controlled substance and schedule. Except to the extent a greater minimum sentence is otherwise provided by section 401(b), a term of imprisonment under this subsection shall be not less than one year. Penalties for third and subsequent convictions shall be governed by section 401(b)(1)(A).

SEC. 419. [21 U.S.C. 860] DISTRIBUTION IN OR NEAR SCHOOLS[55] (a) Any person who violates section 401(a)(1) or section 416 by distributing, possessing with intent to distribute, or manufacturing a controlled substance in or on, or within one thousand feet of, the real property comprising a public or private elementary, vocational, or secondary school or a public or private college, junior college, or university, or a playground, or housing facility owned by a public housing authority, or within 100 feet of a public or private youth center, public swimming pool, or video arcade facility, is (except as provided in subsection (b)) subject to (1) twice the maximum punishment authorized by section 401(b) of this title; and (2) at least twice any term of supervised release authorized by section 401(b) for a first offense. A fine up to twice that authorized by section 401(b) may be imposed in addition to any term of imprisonment authorized by this subsection. Except to the extent a greater minimum sentence is otherwise provided by section 401(b), a person shall be sentenced under this subsection to a term of imprisonment of not less than one year. The mandatory minimum sentencing provisions of this paragraph shall not apply to offenses involving 5 grams or less of marihuana.

(b) Any person who violates section 401(a)(1) or section 416 by distributing, possessing with intent to distribute, or manufacturing a controlled substance in or on, or within one thousand feet of, the real property comprising a public or private elementary, vocational, or secondary school or a public or private college, junior college, or university, or a playground, or housing facility owned by a public housing authority, or within 100 feet of a public or private youth center, public swimming pool, or video arcade facility, after a prior conviction under subsection (a) has become final is punishable (1) by the greater of (A) a term of imprisonment of not less than three years and not more than life imprisonment or (B) three times the maximum punishment authorized by section 401(b) for a first offense, and (2) at least three times any term of supervised release authorized by section 401(b) of this title for a first offense. A fine up to three times that authorized by section 401(b) may be imposed in addition to any term of imprisonment authorized by this subsection. Except to the extent a greater minimum sentence is otherwise provided by section 401(b), a person shall be sentenced under this subsection to a term of imprisonment of not less than three years. Penalties for third and subsequent convictions shall be governed by section 401(b)(1)(A).

(c) Notwithstanding any other law, any person at least 21 years of age who knowingly and intentionally—

(1) employs, hires, uses, persuades, induces, entices, or coerces a person under 18 years of age to violate this section; or

(2) employs, hires, uses, persuades, induces, entices, or coerces a person under 18 years of age to assist in avoiding detection or apprehension for any offense under this section by any Federal, State, or local law enforcement official,

is punishable by a term of imprisonment, a fine, or both, up to triple those authorized by section 401.

[55] So in law. Probably should be "DISTRIBUTION OR MANUFACTURING IN OR NEAR SCHOOLS AND COLLEGES". Public Law 99–570 added references to manufacturing and to colleges.

(d) In the case of any mandatory minimum sentence imposed under subsection (b)[56], imposition or execution of such sentence shall not be suspended and probation shall not be granted. An individual convicted under this section shall not be eligible for parole until the individual has served the mandatory minimum term of imprisonment as provided by this section.

(e) For the purposes of this section—

(1) The term "playground" means any outdoor facility (including any parking lot appurtenant thereto) intended for recreation, open to the public, and with any portion thereof containing three or more separate apparatus intended for the recreation of children including, but not limited to, sliding boards, swingsets, and teeterboards.

(2) The term "youth center" means any recreational facility and/or gymnasium (including any parking lot appurtenant thereto), intended primarily for use by persons under 18 years of age, which regularly provides athletic, civic, or cultural activities.

(3) The term "video arcade facility" means any facility, legally accessible to persons under 18 years of age, intended primarily for the use of pinball and video machines for amusement containing a minimum of ten pinball and/or video machines.

(4) The term "swimming pool" includes any parking lot appurtenant thereto.

CONSECUTIVE SENTENCE FOR MANUFACTURING OR DISTRIBUTING, OR POSSESSING WITH INTENT TO MANUFACTURE OR DISTRIBUTE, METHAMPHETAMINE ON PREMISES WHERE CHILDREN ARE PRESENT OR RESIDE

SEC. 419a. [21 U.S.C. 860a] Whoever violates section 401(a)(1) by manufacturing or distributing, or possessing with intent to manufacture or distribute, methamphetamine or its salts, isomers or salts of isomers on premises in which an individual who is under the age of 18 years is present or resides, shall, in addition to any other sentence imposed, be imprisoned for a period of any term of years but not more than 20 years, subject to a fine, or both.

EMPLOYMENT OR USE OF PERSONS UNDER 18 YEARS OF AGE IN DRUG OPERATIONS

SEC. 420. [21 U.S.C. 861] (a) It shall be unlawful for any person at least eighteen years of age to knowingly and intentionally—

(1) employ, hire, use, persuade, induce, entice, or coerce, a person under eighteen years of age to violate any provision of this title or title III;

[56] Section 1214(3)(B) of Public Law 101–647 (104 Stat. 4833) attempted to strike "subsection (b) of", with the apparent intent for the language to read "under this section" rather than "under subsection (b)", but the amendment cannot be executed because the phrase "subsection (b) of" does not appear. See section 503(a) of Public Law 98–473 (98 Stat. 2069), which added section 419. (The section was added as section 405A, and was redesignated as section 419 by section 1002(b) of Public Law 101–647 (104 Stat. 4827).) (The amendment described in section 1214(3)(B) of Public Law 101–647 is directed to section "419(c)". Subsection (d) above formerly was subsection (c), and was redesignated as subsection (d) by section 140006 of Public Law 103–322 (108 Stat. 2032).)

(2) employ, hire, use persuade, induce, entice, or coerce, a person under eighteen years of age to assist in avoiding detection or apprehension for any offense of this title or title III by any Federal, State, or local law enforcement official; or

(3) receive a controlled substance from a person under 18 years of age, other than an immediate family member, in violation of this title or title III.

(b) Any person who violates subsection (a) is punishable by a term of imprisonment up to twice that otherwise authorized, or up to twice the fine otherwise authorized, or both [57], and at least twice any term of supervised release otherwise authorized for a first offense. Except to the extent a greater minimum sentence is otherwise provided, a term of imprisonment under this subsection shall not be less than one year.

(c) Any person who violates subsection (a) after a prior conviction under subsection (a) of this section has become final, is punishable by a term of imprisonment up to three times that otherwise authorized, or both [57], and at least three times any term of supervised release otherwise authorized for a first offense. Except to the extent a greater minimum sentence is otherwise provided, a term of imprisonment under this subsection shall not be less than one year. Penalties for third and subsequent convictions shall be governed by section 401(b)(1)(A).

(d) Any person who violates section 405B(a) (1) or (2) [58]

(1) by knowingly providing or distributing a controlled substance or a controlled substance analogue to any person under eighteen years of age; or

(2) if the person employed, hired, or used is fourteen years of age or younger.

shall be subject to a term of imprisonment for not more than five years or a fine of not more than $50,000, or both, in addition to any other punishment authorized by this section.

(e) In any case of any sentence imposed under this section, imposition or execution of such sentence shall not be suspended and probation shall not be granted. An individual convicted under this section of an offense for which a mandatory minimum term of imprisonment is applicable shall not be eligible for parole under section 4202 of title 18, United States Code, [59] until the individual has served the mandatory term of imprisonment as enhanced by this section.

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[57] Section 1003(c) of Public Law 101–647 (104 Stat. 4829) attempted in each of subsections (b) and (c) above to strike a certain phrase and insert another, but the amendments cannot be executed because the phrase to be struck did not appear.

In subsection (b), the phrase to be struck was "is punishable by a term of imprisonment up to twice that authorized, or up to twice the fine authorized, or both,", which does not appear. The language to be inserted was "is subject to twice the maximum punishment otherwise authorized".

In subsection (c), the phrase to be struck was "is punishable by a term of imprisonment up to three times that authorized, or up to three times the fine authorized, or both,", which does not appear. The language to be inserted was "is subject to three times the maximum punishment otherwise authorized".

[58] So in law. Probably should be followed by a dash.

[59] Section 4202 of title 18, United States Code, was repealed by section 218(a)(5) of Public Law 98–473 (98 Stat. 2027). For information on effective dates relating to such repeal, see the notes in the United States Code relating to former sections 4201 through 4218 of title 18 (former chapter 311).

(f) Except as authorized by this title, it shall be unlawful for any person to knowingly or intentionally provide or distribute any controlled substance to a pregnant individual in violation of any provision of this title. Any person who violates this subsection shall be subject to the provisions of subsections (b), (c), and (e).

SEC. 421. [21 U.S.C. 862] DENIAL OF FEDERAL BENEFITS TO DRUG TRAFFICKERS AND POSSESSORS.

(a) DRUG TRAFFICKERS.—(1) Any individual who is convicted of any Federal or State offense consisting of the distribution of controlled substances shall—

(A) at the discretion of the court, upon the first conviction for such an offense be ineligible for any or all Federal benefits for up to 5 years after such conviction;

(B) at the discretion of the court, upon a second conviction for such an offense be ineligible for any or all Federal benefits for up to 10 years after such conviction; and

(C) upon a third or subsequent conviction for such an offense be permanently ineligible for all Federal benefits.

(2) The benefits which are denied under this subsection shall not include benefits relating to long-term drug treatment programs for addiction for any person who, if there is a reasonable body of evidence to substantiate such declaration, declares himself to be an addict and submits himself to a long-term treatment program for addiction, or is deemed to be rehabilitated pursuant to rules established by the Secretary of Health and Human Services.

(b) DRUG POSSESSORS.—(1) Any individual who is convicted of any Federal or State offense involving the possession of a controlled substance (as such term is defined for purposes of the Controlled Substances Act) shall—

(A) upon the first conviction for such an offense and at the discretion of the court—

(i) be ineligible for any or all Federal benefits for up to one year;

(ii) be required to successfully complete an approved drug treatment program which includes periodic testing to insure that the individual remains drug free;

(iii) be required to perform appropriate community service; or

(iv) any combination of clauses (i), (ii), or (iii); and

(B) upon a second or subsequent conviction for such an offense be ineligible for all Federal benefits for up to 5 years after such conviction as determined by the court. The court shall continue to have the discretion in subparagraph (A) above. In imposing penalties and conditions under subparagraph (A), the court may require that the completion of the conditions imposed by clause (ii) and (iii) be a requirement for the reinstatement of benefits under clause (i).

(2) The penalties and conditions which may be imposed under this subsection shall be waived in the case of a person who, if there is a reasonable body of evidence of substantiate such declaration, declares himself to be an addict and submits himself to a long-term treatment program for addiction, or is deemed to be rehabilitated pursuant to rules established by the Secretary of Health and Human Services.

(c) SUSPENSION OF PERIOD OF INELIGIBILITY.—The period of ineligibility referred to in subsections (a) and (b) shall be suspended if the individual—

(A) completes a supervised drug rehabilitation program after becoming ineligible under this section;

(B) has otherwise been rehabilitated; or

(C) has made a good faith effort to gain admission to a supervised drug rehabilitation program, but is unable to do so because of inaccessibility or unavailability of such a program, or the inability of the individual to pay for such a program.

(d) DEFINITIONS.—As used in this section—

(1) the term "Federal benefit"—

(A) means the issuance of any grant, contract, loan, professional license, or commercial license provided by an agency of the United States or by appropriated funds of the United States; and

(B) does not include any retirement, welfare, Social Security, health, disability, veterans benefit, public housing, or other similar benefit, or any other benefit for which payments or services are required for eligibility; and

(2) the term "veterans benefit" means all benefits provided to veterans, their families, or survivors by virtue of the service of a veteran in the Armed Forces of the United States.

(e) INAPPLICABILITY OF THIS SECTION TO GOVERNMENT WITNESSES.—The penalties provided by this section shall not apply to any individual who cooperates or testifies with the Government in the prosecution of a Federal or State offense or who is in a Government witness protection program.

(f) INDIAN PROVISION.—Nothing in this section shall be construed to affect the obligation of the United States to any Indian or Indian tribe arising out of any treaty, statute, Executive order, or the trust responsibility of the United States owing to such Indian or Indian tribe. Nothing in this subsection shall exempt any individual Indian from the sanctions provided for in this section, provided that no individual Indian shall be denied any benefit under Federal Indian programs comparable to those described in subsection (d)(1)(B) or (d)(2) above.

(g) PRESIDENTIAL REPORT.—(1) On or before May 1, 1989, the President shall transmit to the Congress a report—

(A) delineating the role of State courts in implementing this section;

(B) describing the manner in which Federal agencies will implement and enforce the requirements of this section;

(C) detailing the means by which Federal and State agencies, courts, and law enforcement agencies will exchange and share the data and information necessary to implement and enforce the withholding of Federal benefits; and

(D) recommending any modifications to improve the administration of this section or otherwise achieve the goal of discouraging the trafficking and possession of controlled substances.

(2) No later than September 1, 1989, the Congress shall consider the report of the President and enact such changes as it deems appropriate to further the goals of this section.

(h) EFFECTIVE DATE.—The denial of Federal benefits set forth in this section shall take effect for convictions occurring after September 1, 1989.

DRUG PARAPHERNALIA

SEC. 422. [21 U.S.C. 863] (a) It is unlawful for any person—

(1) to sell or offer for sale drug paraphernalia;

(2) to use the mails or any other facility of interstate commerce to transport drug paraphernalia; or

(3) to import or export drug paraphernalia.

(b) Anyone convicted of an offense under subsection (a) of this section shall be imprisoned for not more than three years and fined under title 18, United States Code.

(c) Any drug paraphernalia involved in any violation of subsection (a) of this section shall be subject to seizure and forfeiture upon the conviction of a person for such violation. Any such paraphernalia shall be delivered to the Administrator of General Services, General Services Administration, who may order such paraphernalia destroyed or may authorize its use for law enforcement or educational purposes by Federal, State, or local authorities.

(d) The term "drug paraphernalia" means any equipment, product, or material of any kind which is primarily intended or designed for use in manufacturing, compounding, converting, concealing, producing, processing, preparing, injecting, ingesting, inhaling, or otherwise introducing into the human body a controlled substance, possession of which is unlawful under the Controlled Substances Act (title II of Public Law 91–513). It includes items primarily intended or designed for use in ingesting, inhaling, or otherwise introducing marijuana[60], cocaine, hashish, hashish oil, PCP, methamphetamine, or amphetamines into the human body, such as—

(1) metal, wooden, acrylic, glass, stone, plastic, or ceramic pipes with or without screens, permanent screens, hashish heads, or punctured metal bowls;

(2) water pipes;

(3) carburetion tubes and devices;

(4) smoking and carburetion masks;

(5) roach clips: meaning objects used to hold burning material, such as a marihuana cigarette, that has become too small or too short to be held in the hand;

(6) miniature spoons with level capacities of one-tenth cubic centimeter or less;

(7) chamber pipes;

(8) carburetor pipes;

(9) electric pipes;

(10) air-driven pipes;

(11) chillums;

(12) bongs;

[60] So in law. Probably should be "marihuana". See the list of substances in schedule I under section 202(c).

(13) ice pipes or chillers;
(14) wired cigarette papers; or
(15) cocaine freebase kits.

(e) In determining whether an item constitutes drug paraphernalia, in addition to all other logically relevant factors, the following may be considered:

(1) instructions, oral or written, provided with the item concerning its use;
(2) descriptive materials accompanying the item which explain or depict its use;
(3) national and local advertising concerning its use;
(4) the manner in which the item is displayed for sale;
(5) whether the owner, or anyone in control of the item, is a legitimate supplier of like or related items to the community, such as a licensed distributor or dealer of tobacco products;
(6) direct or circumstantial evidence of the radio of sales of the item(s) to the total sales of the business enterprise;
(7) the existence and scope of legitimate uses of the item in the community; and
(8) expert testimony concerning its use.

(f) This section shall not apply to—

(1) any person authorized by local, State, or Federal law to manufacture, possess, or distribute such items; or
(2) any item that, in the normal lawful course of business, is imported, exported, transported, or sold through the mail or by any other means, and traditionally intended for use with tobacco products, including any pipe, paper, or accessory.

ANHYDROUS AMMONIA

SEC. 423. [21 U.S.C. 864] (a) It is unlawful for any person—

(1) to steal anhydrous ammonia, or
(2) to transport stolen anhydrous ammonia across State lines,

knowing, intending, or having reasonable cause to believe that such anhydrous ammonia will be used to manufacture a controlled substance in violation of this part.

(b) Any person who violates subsection (a) shall be imprisoned or fined, or both, in accordance with section 403(d) as if such violation were a violation of a provision of section 403.

PART E—ADMINISTRATIVE AND ENFORCEMENT PROVISIONS

PROCEDURES

SEC. 501. [21 U.S.C. 871] (a) The Attorney General may delegate any of his functions under this title to any officer or employee of the Department of Justice.

(b) The Attorney General may promulgate and enforce any rules, regulations, and procedures which he may deem necessary and appropriate for the efficient execution of his functions under this title.

(c) The Attorney General may accept in the name of the Department of Justice any form of devise, bequest, gift, or donation where the donor intends to donate property for the purpose of pre-

venting or controlling the abuse of controlled substances. He may take all appropriate steps to secure possession of such property and may sell, assign, transfer, or convey any such property other than moneys.

EDUCATION AND RESEARCH PROGRAMS OF THE ATTORNEY GENERAL

SEC. 502. [21 U.S.C. 872] (a) The Attorney General is authorized to carry out educational and research programs directly related to enforcement of the laws under his jurisdiction concerning drugs or other substances which are or may be subject to control under this title. Such programs may include—

(1) educational and training programs on drug abuse and controlled substances law enforcement for local, State, tribal, and Federal personnel;

(2) studies or special projects designed to compare the deterrent effects of various enforcement strategies on drug use and abuse;

(3) studies or special projects designed to assess and detect accurately the presence in the human body of drugs or other substances which are or may be subject to control under this title, including the development of rapid field identification methods which would enable agents to detect microquantities of such drugs or other substances;

(4) studies or special projects designed to evaluate the nature and sources of the supply of illegal drugs throughout the country;

(5) studies or special projects to develop more effective methods to prevent diversion of controlled substances into illegal channels; and

(6) studies or special projects to develop information necessary to carry out his functions under section 201 of this title.

(b) The Attorney General may enter into contracts for such educational and research activities without performance bonds and without regard to section 3709 of the Revised Statutes (41 U.S.C. 5).

(c) The Attorney General may authorize persons engaged in research to withhold the names and other identifying characteristics of persons who are the subjects of such research. Persons who obtain this authorization may not be compelled in any Federal, State, tribal, or local civil, criminal, administrative, legislative, or other proceeding to identify the subjects of research for which such authorization was obtained.

(d)[61] Nothing in the Single Convention on Narcotic Drugs, the Convention on Psychotropic Substances, or other treaties or international agreements shall be construed to limit, modify, or prevent the protection of the confidentiality of patient records or of the names and other identifying characteristics of research subjects as provided by any Federal, State, or local law or regulation.

[61] Subsection (d) was added by title I of Public Law 95–633. Section 112 of such Public Law provided as follows: "This title 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.". The Convention entered into force in respect to the United States on July 15, 1980.

(e) The Attorney General, on his own motion or at the request of the Secretary, may authorize the possession, distribution, and dispensing of controlled substances by persons engaged in research. Persons who obtain this authorization shall be exempt from State or Federal prosecution for possession, distribution, and dispensing of controlled substances to the extent authorized by the Attorney General.

(f) The Attorney General shall maintain an active program, both domestic and international, to curtail the diversion of precursor chemicals and essential chemicals used in the illicit manufacture of controlled substances.

COOPERATIVE ARRANGEMENTS

SEC. 503. [21 U.S.C. 873] (a) The Attorney General shall cooperate with local, State, tribal, and Federal agencies concerning traffic in controlled substances and in suppressing the abuse of controlled substances. To this end, he is authorized to—

(1) arrange for the exchange of information between governmental officials concerning the use and abuse of controlled substances;

(2) cooperate in the institution and prosecution of cases in the courts of the United States and before the licensing boards and courts of the several States;

(3) conduct training programs on controlled substance law enforcement for local, State, tribal, and Federal personnel;

(4) maintain in the Department of Justice a unit which will accept, catalog, file, and otherwise utilize all information and statistics, including records of controlled substance abusers and other controlled substance law offenders, which may be received from Federal, State, tribal, and local agencies, and make such information available for Federal, State, tribal, and local law enforcement purposes;

(5) conduct programs of eradication aimed at destroying wild or illicit growth of plant species from which controlled substances may be extracted;

(6) assist State, tribal, and local governments in suppressing the diversion of controlled substances from legitimate medical, scientific, and commercial channels by—

(A) making periodic assessments of the capabilities of State, tribal, and local governments to adequately control the diversion of controlled substances;

(B) providing advice and counsel to State, tribal, and local governments on the methods by which such governments may strengthen their controls against diversion; and

(C) establishing cooperative investigative efforts to control diversion; and

(7) notwithstanding any other provision of law, enter into contractual agreements with State, tribal, and local law enforcement agencies to provide for cooperative enforcement and regulatory activities under this Act.

(b) When requested by the Attorney General, it shall be the duty of any agency or instrumentality of the Federal Government

to furnish assistance, including technical advice, to him for carrying out his functions under this title; except that no such agency or instrumentality shall be required to furnish the name of, or other identifying information about, a patient or research subject whose identity it has undertaken to keep confidential.

(c)(1) The Attorney General shall, once every 6 months, prepare and make available to regulatory, licensing, attorneys general, and law enforcement agencies of States a standardized report containing descriptive and analytic information on the actual distribution patterns, as gathered through the Automated Reports and Consolidated Orders System, or any subsequent automated system, pursuant to section 307 and which includes detailed amounts, outliers, and trends of distributor and pharmacy registrants, in such States for the controlled substances contained in schedule II, which, in the discretion of the Attorney General, are determined to have the highest abuse.

(2) If the Attorney General publishes the report described in paragraph (1) once every 6 months as required under paragraph (1), nothing in this subsection shall be construed to bring an action in any court to challenge the sufficiency of the information or to compel the Attorney General to produce any documents or reports referred to in this subsection.

(d)(1) The Attorney General may make grants, in accordance with paragraph (2), to State, tribal, and local governments to assist in meeting the costs of—

(A) collecting and analyzing data on the diversion of controlled substances,

(B) conducting investigations and prosecutions of such diversions,

(C) improving regulatory controls and other authorities to control such diversions,

(D) programs to prevent such diversions,

(E) preventing and detecting forged prescriptions, and

(F) training law enforcement and regulatory personnel to improve the control of such diversions.

(2) No grant may be made under paragraph (1) unless an application therefor is submitted to the Attorney General in such form and manner as the Attorney General may prescribe. No grant may exceed 80 per centum of the costs for which the grant is made, and no grant may be made unless the recipient of the grant provides assurances satisfactory to the Attorney General that it will obligate funds to meet the remaining 20 per centum of such costs. The Attorney General shall review the activities carried out with grants under paragraph (1) and shall report annually to Congress on such activities.

(3) To carry out this subsection there is authorized to be appropriated $6,000,000 for fiscal year 1985 and $6,000,000 for fiscal year 1986.

ADVISORY COMMITTEES

SEC. 504. [21 U.S.C. 874] The Attorney General may from time to time appoint committees to advise him with respect to preventing and controlling the abuse of controlled substances. Mem-

bers of the committees may be entitled to receive compensation at the rate of $100 for each day (including traveltime) during which they are engaged in the actual performance of duties. While traveling on official business in the performance of duties for the committees, members of the committees shall be allowed expenses of travel, including per diem instead of subsistence, in accordance with subchapter I of chapter 57 of title 5, United States Code.

ADMINISTRATIVE HEARINGS

SEC. 505. [21 U.S.C. 875] (a) In carrying out his functions under this title, the Attorney General may hold hearings, sign and issue subpenas, administer oaths, examine witnesses, and receive evidence at any place in the United States.

(b) Except as otherwise provided in this title, notice shall be given and hearings shall be conducted under appropriate procedures of subchapter II of chapter 5, title 5, United States Code.

SUBPENAS

SEC. 506. [21 U.S.C. 876] (a) In any investigation relating to his functions under this title with respect to controlled substances, listed chemicals, tableting machines, or encapsulating machines, the Attorney General may subpena witnesses, compel the attendance and testimony of witnesses, and require the production of any records (including books, papers, documents, and other tangible things which constitute or contain evidence) which the Attorney General finds relevant or material to the investigation. The attendance of witnesses and the production of records may be required from any place in any State or in any territory or other place subject to the jurisdiction of the United States at any designated place of hearing; except that a witness shall not be required to appear at any hearing more than 500 miles distant from the place where he was served with a subpena. Witnesses summoned under this section shall be paid the same fees and mileage that are paid witnesses in the courts of the United States.

(b) A subpena issued under this section may be served by any person designated in the subpena to serve it. Service upon a natural person may be made by personal delivery of the subpena to him. Service may be made upon a domestic or foreign corporation or upon a partnership or other unincorporated association which is subject to suit under a common name, by delivering the subpena to an officer, to a managing or general agent, or to any other agent authorized by appointment or by law to receive service of process. The affidavit of the person serving the subpena entered on a true copy thereof by the person serving it shall be proof of service.

(c) In the case of contumacy by or refusal to obey a subpena issued to any person, the Attorney General may invoke the aid of any court of the United States within the jurisdiction of which the investigation is carried on or of which the subpenaed person is an inhabitant, or in which he carries on business or may be found, to compel compliance with the subpena. The court may issue an order requiring the subpenaed person to appear before the Attorney General to produce records, if so ordered, or to give testimony touching the matter under investigation. Any failure to obey the order of the

court may be punished by the court as a contempt thereof. All process in any such case may be served in any judicial district in which such person may be found.

JUDICIAL REVIEW

SEC. 507. [21 U.S.C. 877] All final determinations, findings, and conclusions of the Attorney General under this title shall be final and conclusive decisions of the matters involved, except that any person aggrieved by a final decision of the Attorney General may obtain review of the decision in the United States Court of Appeals for the District of Columbia or for the circuit in which his principal place of business is located upon petition filed with the court and delivered to the Attorney General within thirty days after notice of the decision. Findings of fact by the Attorney General, if supported by substantial evidence, shall be conclusive.

POWERS OF ENFORCEMENT PERSONNEL

SEC. 508. (a)(a)[62] Any officer or employee of the Drug Enforcement Administration or any State, tribal,[63] or local law enforcement officer or (with respect to offenses under this title or title III) any State, tribal,[63] or local law enforcement officer[62] designated by the Attorney General may—

(1) carry firearms;

(2) execute and serve search warrants, arrest warrants, administrative inspection warrants, subpenas, and summonses issued under the authority of the United States;

(3) make arrests without warrant (A) for any offense against the United States committed in his presence, or (B) for any felony, cognizable under the laws of the United States, if he has probable cause to believe that the person to be arrested has committed or is committing a felony;

(4) make seizures of property pursuant to the provisions of this title; and

(5) perform such other law enforcement duties as the Attorney General may designate.

(b) State and local law enforcement officers performing functions under this section shall not be deemed Federal employees and shall not be subject to provisions of law relating to Federal employees, except that such officers shall be subject to section 3374(c) of title 5, United States Code.

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[62] Two Public Laws in the 99th Congress amended section 508, and the amendments made by the two were substantially similar. The first set of amendments was made by section 1869 of Public Law 99-570 (100 Stat. 3207–55) and the second by section 86 of Public Law 99–646 (100 Stat. 3620).

Both added a subsection (b), and the two subsections are identical. In adding a subsection (b), both designated the pre-existing text of section 508 as subsection (a).

In the matter preceding paragraph (1) of subsection (a), both inserted a reference to "any State or local law enforcement officer". There was one difference between the two: section 1869 inserted the phrase "(with respect to offenses under this title or title III)", while section 86 did not.

The second set of amendments (section 86) was executed to section 508 as such section appeared after the execution of the first set (section 1869).

[63] Section 232(d) of Public Law 111–211 (124 Stat. 2278) provides for an amendment in the matter preceding paragraph (1) by inserting ", tribal," after "State". The amendment did not specify which occurence of the word "State" to insert ", tribal," but was executed to both places such term appears.

(b)[62] State and local law enforcement officers performing functions under this section shall not be deemed Federal employees and shall not be subject to provisions of law relating to Federal employees, except that such officers shall be subject to section 3374(c) of title 5, United States Code.

SEARCH WARRANTS

SEC. 509. [21 U.S.C. 879] A search warrant relating to offenses involving controlled substances may be served at any time of the day or night if the judge or United States magistrate issuing the warrant is satisfied that there is probable cause to believe that grounds exist for the warrant and for its service at such time.

ADMINISTRATIVE INSPECTIONS AND WARRANTS

SEC. 510. [21 U.S.C. 880] (a) As used in this section, the term "controlled premises" means—

(1) places where original or other records or documents required under this title are kept or required to be kept, and

(2) places, including factories, warehouses, and other establishments, and conveyances, where persons registered under section 303 (or exempt from registration under section 302(d) or by regulation of the Attorney General) or regulated persons may lawfully hold, manufacture, distribute, dispense, administer, or otherwise dispose of controlled substances or listed chemicals or where records relating to those activities are maintained.

(b)(1) For the purpose of inspecting, copying, and verifying the correctness of records, reports, or other documents required to be kept or made under this title and otherwise facilitating the carrying out of his functions under this title, the Attorney General is authorized, in accordance with this section, to enter controlled premises and to conduct administrative inspections thereof, and of the things specified in this section, relevant to those functions.

(2) Such entries and inspections shall be carried out through officers or employees (hereinafter referred to as "inspectors") designated by the Attorney General. Any such inspector, upon stating his purpose and presenting to the owner, operator, or agent in charge of such premises (A) appropriate credentials and (B) a written notice of his inspection authority (which notice in the case of an inspection requiring, or in fact supported by, an administrative inspection warrant shall consist of such warrant), shall have the right to enter such premises and conduct such inspection at reasonable times.

(3) Except as may otherwise be indicated in an applicable inspection warrant, the inspector shall have the right—

(A) to inspect and copy records, reports, and other documents required to be kept or made under this title;

(B) to inspect, within reasonable limits and in a reasonable manner, controlled premises and all pertinent equipment, finished and unfinished drugs, listed chemicals, and other substances or materials, containers, and labeling found therein, and, except as provided in paragraph (4) of this subsection, all other things therein (including records, files, papers, processes,

controls, and facilities) appropriate for verification of the records, reports, and documents referred to in clause (A) or otherwise bearing on the provisions of this title; and

(C) to inventory any stock of any controlled substance or listed chemical therein and obtain samples of any such substance or chemical.

(4) Except when the owner, operator, or agent in charge of the controlled premises so consents in writing, no inspection authorized by this section shall extend to—

(A) financial data;

(B) sales data other than shipment data; or

(C) pricing data.

(c) A warrant under this section shall not be required for the inspection of books and records pursuant to an administrative subpena issued in accordance with section 506, nor for entries and administrative inspections (including seizures of property)—

(1) with the consent of the owner, operator, or agent in charge of the controlled premises;

(2) in situations presenting imminent danger to health or safety;

(3) in situations involving inspection of conveyances where there is reasonable cause to believe that the mobility of the conveyance makes it impracticable to obtain a warrant;

(4) in any other exceptional or emergency circumstances where time or opportunity to apply for a warrant is lacking; or

(5) in any other situations where a warrant is not constitutionally required.

(d) Issuance and execution of administrative inspection warrants shall be as follows:

(1) Any judge of the United States or of a State court of record, or any United States magistrate, may, within his territorial jurisdiction, and upon proper oath or affirmation showing probable cause, issue warrants for the purpose of conducting administrative inspections authorized by this title or regulations thereunder, and seizures of property appropriate to such inspections. For the purposes of this section, the term "probable cause" means a valid public interest in the effective enforcement of this title or regulations thereunder sufficient to justify administrative inspections of the area, premises, building, or conveyance, or contents thereof, in the circumstances specified in the application for the warrant.

(2) A warrant shall issue only upon an affidavit of an officer or employee having knowledge of the facts alleged, sworn to before the judge or magistrate and establishing the grounds for issuing the warrant. If the judge or magistrate is satisfied that grounds for the application exist or that there is probable cause to believe they exist, he shall issue a warrant identifying the area, premises, building, or conveyance to be inspected, the purpose of such inspection, and, where appropriate, the type of property to be inspected, if any. The warrant shall identify the items or types of property to be seized, if any. The warrant shall be directed to a person authorized under subsection (b)(2) to execute it. The warrant shall state the grounds for its issuance and the name of the person or persons whose affidavit has been taken in support thereof. It shall command the person to whom it is directed to inspect the area, prem-

ises, building, or conveyance identified for the purpose specified, and, where appropriate, shall direct the seizure of the property specified. The warrant shall direct that it be served during normal business hours. It shall designate the judge or magistrate to whom it shall be returned.

(3) A warrant issued pursuant to this section must be executed and returned within ten days of its date unless, upon a showing by the United States of a need therefor, the judge or magistrate allows additional time in the warrant. If property is seized pursuant to a warrant, the person executing the warrant shall give to the person from whom or from whose premises the property was taken a copy of the warrant and a receipt for the property taken or shall leave the copy and receipt at the place from which the property was taken. The return of the warrant shall be made promptly and shall be accompanied by a written inventory of any property taken. The inventory shall be made in the presence of the person executing the warrant and of the person from whose possession or premises the property was taken, if they are present, or in the presence of at least one credible person other than the person making such inventory, and shall be verified by the person executing the warrant. The judge or magistrate, upon request, shall deliver a copy of the inventory to the person from whom or from whose premises the property was taken and to the applicant for the warrant.

(4) The judge or magistrate who has issued a warrant under this section shall attach to the warrant a copy of the return and all papers filed in connection therewith and shall file them with the clerk of the district court of the United States for the judicial district in which the inspection was made.

FORFEITURES

SEC. 511. [21 U.S.C. 881] (a) The following shall be subject to forfeiture to the United States and no property right shall exist in them:

(1) All controlled substances which have been manufactured, distributed, dispensed, or acquired in violation of this title.

(2) All raw materials, products, and equipment of any kind which are used, or intended for use, in manufacturing, compounding, processing, delivering, importing, or exporting any controlled substance or listed chemical in violation of this title.

(3) All property which is used, or intended for use, as a container for property described in paragraph (1), (2), or (9).

(4) All conveyances, including aircraft, vehicles, or vessels, which are used, or are intended for use, to transport, or in any manner to facilitate the transportation, sale, receipt, possession, or concealment of property described in paragraph (1), (2), or (9).

(5) All books, records, and research, including formulas, microfilm, tapes, and data which are used, or intended for use, in violation of this title.

(6) All moneys, negotiable instruments, securities, or other things of value furnished or intended to be furnished by any person in exchange for a controlled substance or listed chemical in violation of this title, all proceeds traceable to such an exchange, and all moneys, negotiable instruments, and securities used or intended to be used to facilitate any violation of this title.

(7) All real property, including any right, title, and interest (including any leasehold interest) in the whole of any lot or tract of land and any appurtenances or improvements, which is used, or intended to be used, in any manner or part, to commit, or to facilitate the commission of, a violation of this title punishable by more than one year's imprisonment.

(8) All controlled substances which have been possessed in violation of this title.

(9) All listed chemicals, all drug manufacturing equipment, all tableting machines, all encapsulating machines, and all gelatin capsules, which have been imported, exported, manufactured, possessed, distributed, dispensed, acquired,or intended to be distributed, dispensed, acquired, imported, or exported, in violation of this title or title III.

(10) Any drug paraphernalia (as defined in section 422).

(11) Any firearm (as defined in section 921 of title 18, United States Code) used or intended to be used to facilitate the transportation, sale, receipt, possession, or concealment of property described in paragraph (1) or (2) and any proceeds traceable to such property.

(b) SEIZURE PROCEDURES.—Any property subject to forfeiture to the United States under this section may be seized by the Attorney General in the manner set forth in section 981(b) of title 18, United States Code.

(c) Property taken or detained under this section shall not be repleviable, but shall be deemed to be in the custody of the Attorney General, subject only to the orders and decrees of the court or the official having jurisdiction thereof. Whenever property is seized under any of the provisions of this title, the Attorney General may—

(1) place the property under seal;

(2) remove the property to a place designated by him; or

(3) require that the General Services Administration take custody of the property and remove it, if practicable, to an appropriate location for disposition in accordance with law.

(d) The provisions of law relating to the seizure, summary and judicial forfeiture, and condemnation of property for violation of the customs laws; the disposition of such property or the proceeds from the sale thereof; the remission or mitigation of such forfeitures; and the compromise of claims shall apply to seizures and forfeitures incurred, or alleged to have been incurred, under any of the provisions of this title, insofar as applicable and not inconsistent with the provisions hereof; except that such duties as are imposed upon the customs officer or any other person with respect to the seizure and forfeiture of property under the customs laws shall be performed with respect to seizures and forfeitures of property under this title by such officers, agents, or other persons as may be au-

thorized or designated for that purpose by the Attorney General, except to the extent that such duties arise from seizures and forfeitures effected by any customs officer.

(e)(1) Whenever property is civilly or criminally forfeited under this title the Attorney General may—

(A) retain the property for official use or, in the manner provided with respect to transfers under section 616 of the Tariff Act of 1930, transfer the property to any Federal agency or to any State or local law enforcement agency which participated directly in the seizure or forfeiture of the property;

(B) except as provided in paragraph (4), sell, by public sale or any other commercially feasible means, any forfeited property which is not required to be destroyed by law and which is not harmful to the public;

(C) require that the General Services Administration take custody of the property and dispose of it in accordance with law;

(D) forward it to the Bureau of Narcotics and Dangerous Drugs for disposition (including delivery for medical or scientific use to any Federal or State agency under regulations of the Attorney General); or

(E) transfer the forfeited personal property or the proceeds of the sale of any forfeited personal or real property to any foreign country which participated directly or indirectly in the seizure or forfeiture of the property, if such a transfer—

(i) has been agreed to by the Secretary of State;

(ii) is authorized in an international agreement between the United States and the foreign country; and

(iii) is made to a country which, if applicable, has been certified under section 490(b) of the Foreign Assistance Act of 1961.

(2)(A) The proceeds from any sale under subparagraph (B) of paragraph (1) and any moneys forfeited under this title shall be used to pay—

(i) all proper expenses of the proceedings for forfeiture and sale including expenses of seizure, maintenance of custody, advertising, and court costs; and

(ii) awards of up to $100,000 to any individual who provides original information which leads to the arrest and conviction of a person who kills or kidnaps a Federal drug law enforcement agent.

Any award paid for information concerning the killing or kidnapping of a Federal drug law enforcement agent, as provided in clause (ii), shall be paid at the discretion of the Attorney General.

(B) The Attorney General shall forward to the Treasurer of the United States for deposit in accordance with section 524(c) of title 28, United States Code, any amounts of such moneys and proceeds remaining after payment of the expenses provided in subparagraph (A), except that, with respect to forfeitures conducted by the Postal Service, the Postal Service shall deposit in the Postal Service Fund, under section 2003(b)(7) of title 39, United States Code, such moneys and proceeds.

(3) The Attorney General shall assure that any property transferred to a State or local law enforcement agency under paragraph (1)(A)—

(A) has a value that bears a reasonable relationship to the degree of direct participation of the State or local agency in the law enforcement effort resulting in the forfeiture, taking into account the total value of all property forfeited and the total law enforcement effort with respect to the violation of law on which the forfeiture is based; and

(B) will serve to encourage further cooperation between the recipient State or local agency and Federal law enforcement agencies.

(4)(A) With respect to real property described in subparagraph (B), if the chief executive officer of the State involved submits to the Attorney General a request for purposes of such subparagraph, the authority established in such subparagraph is in lieu of the authority established in paragraph (1)(B).

(B) In the case of property described in paragraph (1)(B) that is civilly or criminally forfeited under this title, if the property is real property that is appropriate for use as a public area reserved for recreational or historic purposes or for the preservation of natural conditions, the Attorney General, upon the request of the chief executive officer of the State in which the property is located, may transfer title to the property to the State, either without charge or for a nominal charge, through a legal instrument providing that—

(i) such use will be the principal use of the property; and

(ii) title to the property reverts to the United States in the event that the property is used otherwise.

(f)(1) All controlled substances in schedule I or II that are possessed, transferred, sold, or offered for sale in violation of the provisions of this title; all dangerous, toxic, or hazardous raw materials or products subject to forfeiture under subsection (a)(2) of this section; and any equipment or container subject to forfeiture under subsection (a)(2) or (3) which cannot be separated safely from such raw materials or products shall be deemed contraband and seized and summarily forfeited to the United States. Similarly, all substances in schedule I or II, which are seized or come into the possession of the United States, the owners of which are unknown, shall be deemed contraband and summarily forfeited to the United States.

(2) The Attorney General may direct the destruction of all controlled substances in schedule I or II seized for violation of this title; all dangerous, toxic, or hazardous raw materials or products subject to forfeiture under subsection (a)(2) of this section; and any equipment or container subject to forfeiture under subsection (a)(2) or (3) which cannot be separated safely from such raw materials or products under such circumstances as the Attorney General may deem necessary.

(g)(1) All species of plants from which controlled substances in schedules I and II may be derived which have been planted or cultivated in violation of this title, or of which the owners or cultivators are unknown, or which are wild growths, may be seized and summarily forfeited to the United States.

(2) The failure, upon demand by the Attorney General or his duly authorized agent, of the person in occupancy or in control of land or premises upon which such species of plants are growing or being stored, to produce an appropriate registration, or proof that he is the holder thereof, shall constitute authority for the seizure and forfeiture.

(3) The Attorney General, or his duly authorized agent, shall have authority to enter upon any lands, or into any dwelling pursuant to a search warrant, to cut, harvest, carry off, or destroy such plants.

(h) All right, title, and interest in property described in subsection (a) shall vest in the United States upon commission of the act giving rise to forfeiture under this section.

(i) The provisions of section 981(g) of title 18, United States Code, regarding the stay of a civil forfeiture proceeding shall apply to forfeitures under this section.

(j) In addition to the venue provided for in section 1395 of title 28, United States Code, or any other provision of law, in the case of property of a defendant charged with a violation that is the basis for forfeiture of the property under this section, a proceeding for forfeiture under this section may be brought in the judicial district in which the defendant owning such property is found or in the judicial district in which the criminal prosecution is brought.

(l)[64] The functions of the Attorney General under this section shall be carried out by the Postal Service pursuant to such agreement as may be entered into between the Attorney General and the Postal Service.

INJUNCTIONS

SEC. 512. [21 U.S.C. 882] (a) The district courts of the United States and all courts exercising general jurisdiction in the territories and possessions of the United States shall have jurisdiction in proceedings in accordance with the Federal Rules of Civil Procedure to enjoin violations of this title.

(b) In case of an alleged violation of an injunction or restraining order issued under this section, trial shall, upon demand of the accused, be by a jury in accordance with the Federal Rules of Civil Procedure.

(c) STATE CAUSE OF ACTION PERTAINING TO ONLINE PHARMACIES.—

(1) IN GENERAL.—In any case in which the State has reason to believe that an interest of the residents of that State has been or is being threatened or adversely affected by the action of a person, entity, or Internet site that violates the provisions of section 303(g), 309(e), or 311, the State may bring a civil action on behalf of such residents in a district court of the United States with appropriate jurisdiction—

(A) to enjoin the conduct which violates this section;

(B) to enforce compliance with this section;

(C) to obtain damages, restitution, or other compensation, including civil penalties under section 402(b); and

[64] So in law. Probably should be "(k)". See section 6253(a) of Public Law 100–690 (102 Stat. 4363).

(D) to obtain such other legal or equitable relief as the court may find appropriate.

(2) SERVICE; INTERVENTION.—

(A) Prior to filing a complaint under paragraph (1), the State shall serve a copy of the complaint upon the Attorney General and upon the United States Attorney for the judicial district in which the complaint is to be filed. In any case where such prior service is not feasible, the State shall serve the complaint on the Attorney General and the appropriate United States Attorney on the same day that the State's complaint is filed in Federal district court of the United States. Such proceedings shall be independent of, and not in lieu of, criminal prosecutions or any other proceedings under this title or any other laws of the United States.

(B) Upon receiving notice respecting a civil action pursuant to this section, the United States shall have the right to intervene in such action and, upon so intervening, to be heard on all matters arising therein, and to file petitions for appeal.

(C) Service of a State's complaint on the United States as required in this paragraph shall be made in accord with the requirements of rule 4(i)(1) of the Federal Rule of Civil Procedure.

(3) POWERS CONFERRED BY STATE LAW.—For purposes of bringing any civil action under paragraph (1), nothing in this Act shall prevent an attorney general of a State from exercising the powers conferred on the attorney general of a State by the laws of such State to conduct investigations or to administer oaths or affirmations or to compel the attendance of witnesses of or the production of documentary or other evidence.

(4) VENUE.—Any civil action brought under paragraph (1) in a district court of the United States may be brought in the district in which the defendant is found, is an inhabitant, or transacts business or wherever venue is proper under section 1391 of title 28, United States Code. Process in such action may be served in any district in which the defendant is an inhabitant or in which the defendant may be found.

(5) NO PRIVATE RIGHT OF ACTION.—No private right of action is created under this subsection.

(6) LIMITATION.—No civil action may be brought under paragraph (1) against—

(A) the United States;

(B) an Indian Tribe or tribal organization, to the extent such tribe or tribal organization is lawfully carrying out a contract or compact under the Indian Self-Determination and Education Assistance Act; or

(C) any employee of the United States or such Indian tribe or tribal organization, provided such agent or employee is acting in the usual course of business or employment, and within the scope of the official duties of such agent or employee therewith.

ENFORCEMENT PROCEEDINGS

SEC. 513. [21 U.S.C. 883] Before any violation of this title is reported by the Administrator of the Drug Enforcement Administration to any United States attorney for institution of a criminal proceeding, the Administrator may require that the person against whom such proceeding is contemplated be given appropriate notice and an opportunity to present his views, either orally or in writing, with regard to such contemplated proceeding.

IMMUNITY AND PRIVILEGE

SEC. 514. [21 U.S.C. 884] (a) Whenever a witness refuses, on the basis of his privilege against self-incrimination, to testify or provide other information in a proceeding before a court or grand jury of the United States, involving a violation of this title, and the person presiding over the proceeding communicates to the witness an order issued under this section, the witness may not refuse to comply with the order on the basis of his privilege against self-incrimination. But no testimony or other information compelled under the order issued under subsection (b) of this section or any information obtained by the exploitation of such testimony or other information, may be used against the witness in any criminal case, including any criminal case brought in a court of a State, except a prosecution for perjury, giving a false statement, or otherwise failing to comply with the order.

(b) In the case of any individual who has been or may be called to testify or provide other information at any proceeding before a court or grand jury of the United States, the United States district court for the judicial district in which the proceeding is or may be held shall issue, upon the request of the United States attorney for such district, an order requiring such individual to give any testimony or provide any other information which he refuses to give or provide on the basis of his privilege against self-incrimination.

(c) A United States attorney may, with the approval of the Attorney General or the Deputy Attorney General, the Associate Attorney General, or any Assistant Attorney General designated by the Attorney General, request an order under subsection (b) when in his judgment—

(1) the testimony or other information from such individual may be necessary to the public interest; and

(2) such individual has refused or is likely to refuse to testify or provide other information on the basis of his privilege against self-incrimination.

BURDEN OF PROOF; LIABILITIES

SEC. 515. [21 U.S.C. 885] (a)(1) It shall not be necessary for the United States to negative any exemption or exception set forth in this title in any complaint, information, indictment, or other pleading or in any trial, hearing, or other proceeding under this title, and the burden of going forward with the evidence with respect to any such exemption or exception shall be upon the person claiming its benefit.

(2) In the case of a person charged under section 404(a) with the possession of a controlled substance, any label identifying such substance for purposes of section 503(b)(2) of the Federal Food, Drug, and Cosmetic Act shall be admissible in evidence and shall be prima facie evidence that such substance was obtained pursuant to a valid prescription from a practitioner while acting in the course of his professional practice.

(b) In the absence of proof that a person is the duly authorized holder of an appropriate registration or order form issued under this title, he shall be presumed not to be the holder of such registration or form, and the burden of going forward with the evidence with respect to such registration or form shall be upon him.

(c) The burden of going forward with the evidence to establish that a vehicle, vessel, or aircraft used in connection with controlled substances in schedule I was used in accordance with the provisions of this title shall be on the persons engaged in such use.

(d) Except as provided in sections 2234 and 2235 of title 18, United States Code, no civil or criminal liability shall be imposed by virtue of this title upon any duly authorized Federal officer lawfully engaged in the enforcement of this title, or upon any duly authorized officer of any State, territory, political subdivision thereof, the District of Columbia, or any possession of the United States, who shall be lawfully engaged in the enforcement of any law or municipal ordinance relating to controlled substances.

PAYMENTS AND ADVANCES

SEC. 516. [21 U.S.C. 886] (a) The Attorney General is authorized to pay any person, from funds appropriated for the Drug Enforcement Administration, for information concerning a violation of this title, such sum or sums of money as he may deem appropriate, without reference to any moieties or rewards to which such person may otherwise be entitled by law.

(b) Moneys expended from appropriations of the Drug Enforcement Administration for purchase of controlled substances and subsequently recovered shall be reimbursed to the current appropriation for the Bureau[65].

(c) The Attorney General is authorized to direct the advance of funds by the Treasury Department in connection with the enforcement of this title. Section 16 of Public Law 96–132 (93 Stat. 1049) amended this title in several other places by striking references to the Bureau of Narcotics and Dangerous Drugs and inserting references to the Drug Enforcement Administration.

(d)(1) There is established in the Treasury a trust fund to be known as the "Drug Pollution Fund" (hereinafter referred to in this subsection as the "Fund"), consisting of amounts appropriated or credited to such Fund under section 401(b)(6).

(2) There are hereby appropriated to the Fund amounts equivalent to the fines imposed under section 401(b)(6).

(3) Amounts in the Fund shall be available, as provided in appropriations Acts, for the purpose of making payments in accord-

[65] So in law. Probably should be "Administration". Section 16 of Public Law 96–132 (93 Stat. 1049) amended this title in several other places by striking references to the Bureau of Narcotics and Dangerous Drugs and inserting references to the Drug Enforcement Administration.

ance with paragraph (4) for the clean up of certain pollution resulting from the actions referred to in section 401(b)(6).

(4)(A) The Secretary of the Treasury, after consultation with the Attorney General, shall make payments under paragraph (3), in such amounts as the Secretary determines appropriate, to the heads of executive agencies or departments that meet the requirements of subparagraph (B).

(B) In order to receive a payment under paragraph (3), the head of an executive agency or department shall submit an application in such form and containing such information as the Secretary of the Treasury shall by regulation require. Such application shall contain a description of the fine imposed under section 401(b)(6), the circumstances surrounding the imposition of such fine, and the type and severity of pollution that resulted from the actions to which such fine applies.

(5) For purposes of subchapter B of chapter 98 of the Internal Revenue Code of 1986, the Fund established under this paragraph shall be treated in the same manner as a trust fund established under subchapter A of such chapter.

COORDINATION AND CONSOLIDATION OF POST-SEIZURE ADMINISTRATION

SEC. 517. [21 U.S.C. 887] The Attorney General and the Secretary of the Treasury shall take such action as may be necessary to develop and maintain a joint plan to coordinate and consolidate post-seizure administration of property seized under this title, title III or provisions of the customs laws relating to controlled substances.

CONTROLLED SUBSTANCES PRODUCTION CONTROL

SEC. 519.[66] [21 U.S.C. 889] (a) As used in this section:

(1) The term "controlled substance" has the same meaning given such term in section 102(6) of the Controlled Substances Act (21 U.S.C. 801(6)).

(2) The term "Secretary" means the Secretary of Agriculture.

(3) The term "State" means each of the fifty States, the District of Columbia, the Commonwealth of Puerto Rico, Guam, the Virgin Islands of the United States, American Samoa, the Commonwealth of the Northern Mariana Islands, or the Trust Territory of the Pacific Islands.

(b) Notwithstanding any other provision of law, following the date of enactment of this Act, any person who is convicted under Federal or State law of planting, cultivation, growing, producing, harvesting, or storing a controlled substance in any crop year shall be ineligible for—

(1) as to any commodity produced during that crop year, and the four succeeding crop years, by such person—

(A) any price support or payment made available under the Agricultural Act of 1949 (7 U.S.C. 1421 et seq.),

[66] Section 518 was repealed by section 2(c)(3) of Public Law 106–185 (114 Stat. 210).

the Commodity Credit Corporation Charter Act (15 U.S.C. 714 et seq.), or any other Act;

(B) a farm storage facility loan made under section 4(h) of the Commodity Credit Corporation Charter Act (15 U.S.C. 714b(h));

(C) crop insurance under the Federal Crop Insurance Act (7 U.S.C. 1501 et seq.);

(D) a disaster payment made under the Agricultural Act of 1949 (7 U.S.C. 1421 et seq.); or

(E) a loan made, insured or guaranteed under the Consolidated Farm and Rural Development Act (7 U.S.C. 1921 et seq.) or any other provision of law administered by the Farmers Home Administration; or

(2) a payment made under section 4 or 5 of the Commodity Credit Corporation Charter Act (15 U.S.C. 714b or 714c) for the storage of an agricultural commodity that is—

(A) produced during that crop year, or any of the four succeeding crop years, by such person; and

(B) acquired by the Commodity Credit Corporation.

(c) Not later than 180 days after the date of enactment of this Act, the Secretary shall issue such regulations as the Secretary determines are necessary to carry out this section, including regulations that—

(1) define the term "person";

(2) govern the determination of persons who shall be ineligible for program benefits under this section; and

(3) protect the interests of tenants and sharecroppers.

SEC. 520. [21 U.S.C. 890] REVIEW OF FEDERAL SALES OF CHEMICALS USABLE TO MANUFACTURE CONTROLLED SUBSTANCES.

A Federal department or agency may not sell from the stocks of the department or agency any chemical which, as determined by the Administrator of the Drug Enforcement Administration, could be used in the manufacture of a controlled substance unless the Administrator certifies in writing to the head of the department or agency that there is no reasonable cause to believe that the sale of the chemical would result in the illegal manufacture of a controlled substance.

PART F—ADVISORY COMMISSION

ESTABLISHMENT OF COMMISSION ON MARIHUANA AND DRUG ABUSE

SEC. 601. [21 U.S.C. 801n] (a) There is established a commission to be known as the Commission on Marihuana and Drug Abuse (hereafter in this section referred to as the "Commission"). The Commission shall be composed of—

(1) two Members of the Senate appointed by the President of the Senate;

(2) two Members of the House of Representatives appointed by the Speaker of the House of Representatives; and

(3) nine members appointed by the President of the United States.

At no time shall more than one of the members appointed under paragraph (1), or more than one of the members appointed under

paragraph (2), or more than five of the members appointed under paragraph (3) be members of the same political party.

(b)(1) The President shall designate one of the members of the Commission as Chairman, and one as Vice Chairman. Seven members of the Commission shall constitute a quorum, but a lesser number may conduct hearings.

(2) Members of the Commission who are Members of Congress or full-time officers or employees of the United States shall serve without additional compensation but shall be reimbursed for travel, subsistence, and other necessary expenses incurred in the performance of the duties vested in the Commission. Members of the Commission from private life shall receive $100 per diem while engaged in the actual performance of the duties vested in the Commission, plus reimbursement for travel, subsistence, and other necessary expenses incurred in the performance of such duties.

(3) The Commission shall meet at the call of the Chairman or at the call of a majority of the members thereof.

(c)(1) The Commission shall have the power to appoint and fix the compensation of such personnel as it deems advisable, without regard to the provisions of title 5, United States Code, governing appointments in the competitive service, and the provisions of chapter 51 and subchapter III of chapter 53 of such title, relating to classification and General Schedule pay rates.

(2) The Commission may procure, in accordance with the provisions of section 3109 of title 5, United States Code, the temporary or intermittent services of experts or consultants. Persons so employed shall receive compensation at a rate to be fixed by the Commission, but not in excess of $75 per diem, including travel time. While away from his home or regular place of business in the performance of services for the Commission, any such person may be allowed travel expenses, including per diem in lieu of subsistence, as authorized by section 5703(b) of title 5, United States Code, for persons in the Government service employed intermittently.

(3) The Commission may secure directly from any department or agency of the United States information necessary to enable it to carry out its duties under this section. Upon request of the Chairman of the Commission, such department or agency shall furnish such information to the Commission.

(d)(1) The Commission shall conduct a study of marihuana including, but not limited to, the following areas:

(A) the extent of use of marihuana in the United States to include its various sources, the number of users, number of arrests, number of convictions, amount of marihuana seized, type of user, nature of use;

(B) an evaluation of the efficacy of existing marihuana laws;

(C) a study of the pharmacology of marihuana and its immediate and long-term effects, both physiological and psychological;

(D) the relationship of marihuana use to aggressive behavior and crime;

(E) the relationship between marihuana and the use of other drugs; and

(F) the international control of marihuana.

(2) Within one year after the date on which funds first become available to carry out this section, the Commission shall submit to the President and the Congress a comprehensive report on its study and investigation under this subsection which shall include its recommendations and such proposals for legislation and administrative action as may be necessary to carry out its recommendations.

(e) The Commission shall conduct a comprehensive study and investigation of the causes of drug abuse and their relative significance. The Commission shall submit to the President and the Congress such interim reports as it deems advisable and shall within two years after the date on which funds first become available to carry out this section submit to the President and the Congress a final report which shall contain a detailed statement of its findings and conclusions and also such recommendations for legislation and administrative actions as it deems appropriate. The Commission shall cease to exist sixty days after the final report is submitted under this subsection.

(f) Total expenditures of the Commission shall not exceed $1,000,000.

PART G—CONFORMING, TRANSITIONAL AND EFFECTIVE DATE, AND GENERAL PROVISIONS

REPEALS AND CONFORMING AMENDMENTS

SEC. 701. (a) Sections 201(v), 301(q), and 511 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(v), 331(q), 360(a)) are repealed.

(b) Subsections (a) and (b) of section 303 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 333) are amended to read as follows:

"SEC. 303. (a) Any person who violates a provision of section 301 shall be imprisoned for not more than one year or fined not more than $1,000, or both.

"(b) Notwithstanding the provisions of subsection (a) of this section, if any person commits such a violation after a conviction of him under this section has become final, or commits such a violation with the intent to defraud or mislead, such person shall be imprisoned for not more than three years or fined not more than $10,000 or both."

(c) Section 304(a)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 334(a)(2)) is amended (1) by striking out clauses (A) and (D), (2) by striking out "of such depressant or stimulant drug or" in clause (C), (3) by adding "and" after the comma at the end of clause (C), and (4) by redesignating clauses (B), (C), and (E) as clauses (A), (B), and (C), respectively.

(d) Section 304(d)(3)(iii) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 334(d)(3)(iii)) is amended by striking out "depressant or stimulant drugs or".

(e) Section 510 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360) is amended (1) in subsection (a) by striking out paragraph (2), by inserting "and" at the end of paragraph (1), and by redesignating paragraph (3) as paragraph (2); (2) by striking out "or in the wholesaling, jobbing, or distributing of any depressant or

stimulant drug" in the first sentence of subsection (b); (3) by striking out the last sentence of subsection (b); (4) by striking out "or in the wholesaling, jobbing, or distributing of any depressant or stimulant drug" in the first sentence of subsection (c); (5) by striking out the last sentence of subsection (c); (6) by striking out "(1)" in subsection (d) and by inserting a period after "drug or drugs" in that subsection and deleting the remainder of that subsection; and (7) by striking out "AND CERTAIN WHOLESALERS" in the section heading.

(f) Section 702 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 372) is amended by striking out "to depressant or stimulant drugs or" in subsection (e).

(g) Section 201(a)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(a)(2)) is amended by inserting a period after "Canal Zone" the first time these words appear and deleting all thereafter in such section 201(a)(2).

(h) The last sentence of section 801(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 381(a)) is amended (1) by striking out "This paragraph" and inserting in lieu thereof "Clause (2) of the third sentence of this paragraph,", and (2) by striking out "section 2 of the Act of May 26, 1922, as amended (U.S.C. 1934, edition, title 21, sec. 173)" and inserting in lieu thereof "the Controlled Substances Import and Export Act".

(i)(1) Section 1114 of title 18, United States Code, is amended by striking out "the Bureau of Narcotics" and inserting in lieu thereof "the Bureau of Narcotics and Dangerous Drugs".

(2) Section 1952 of such title is amended—

(A) by inserting in subsection (b)(1) "or controlled substances (as defined in section 102(6) of the Controlled Substances Act)" immediately following "narcotics"; and

(B) by striking out "or narcotics" in subsection (c).

(j) Subsection (a) of section 302 of the Public Health Service Act (42 U.S.C. 242(a)) is amended to read as follows:

"SEC. 302. (a) In carrying out the purposes of section 301 with respect to drugs the use or misuse of which might result in drug abuse or dependency, the studies and investigations authorized therein shall include the use and misuse of narcotic drugs and other drugs. Such studies and investigations shall further include the quantities of crude opium, coca leaves, and their salts, derivatives, and preparations, and other drugs subject to control under the Controlled Substances Act and Controlled Substances Import and Export Act, together with reserves thereof, necessary to supply the normal and emergency medicinal and scientific requirements of the United States. The results of studies and investigations of the quantities of narcotic drugs or other drugs subject to control under such Acts, together with reserves of such drugs, that are necessary to supply the normal and emergency medicinal and scientific requirements of the United States, shall be reported not later than the first day of April of each year to the Attorney General, to be used at his discretion in determining manufacturing quotas or importation requirements under such Acts."

PENDING PROCEEDINGS

SEC. 702. [21 U.S.C. 321 note] (a) Prosecutions for any violation of law occurring prior to the effective date of section 701 shall not be affected by the repeals or amendments made by such section, or abated by reason thereof.

(b) Civil seizures or forfeitures and injunctive proceedings commenced prior to the effective date of section 701 shall not be affected by the repeals or amendments made by such section, or abated by reason thereof.

(c) All administrative proceedings pending before the Bureau of Narcotics and Dangerous Drugs on the date of enactment of this Act shall be continued and brought to final determination in accord with laws and regulations in effect prior to such date of enactment. Where a drug is finally determined under such proceedings to be a depressant or stimulant drug, as defined in section 201(v) of the Federal Food, Drug, and Cosmetic Act, such drug shall automatically be controlled under this title by the Attorney General without further proceedings and listed in the appropriate schedule after he has obtained the recommendation of the Secretary. Any drug with respect to which such a final determination has been made prior to the date of enactment of this Act which is not listed in section 202 within schedules I through V shall automatically be controlled under this title by the Attorney General without further proceedings, and be listed in the appropriate schedule, after he has obtained the recommendations of the Secretary.

(d) Notwithstanding subsection (a) of this section or section 1103, section 4202 of title 18, United States Code, shall apply to any individual convicted under any of the laws repealed by this title or title III without regard to the terms of any sentence imposed on such individual under such law.

PROVISIONAL REGISTRATION

SEC. 703. [21 U.S.C. 822 note] (a)(1) Any person who—

(A) is engaged in manufacturing, distributing, or dispensing any controlled substance on the day before the effective date of section 302, and

(B) is registered on such day under section 510 of the Federal Food, Drug, and Cosmetic Act or under section 4722 of the Internal Revenue Code of 1954,

shall, with respect to each establishment for which such registration is in effect under any such section, be deemed to have a provisional registration under section 303 for the manufacture, distribution, or dispensing (as the case may be) of controlled substances.

(2) During the period his provisional registration is in effect under this section, the registration number assigned such person under such section 510 or under such section 4722 (as the case may be) shall be his registration number for purposes of section 303 of this title.

(b) The provisions of section 304, relating to suspension and revocation of registration, shall apply to a provisional registration under this section.

(c) Unless sooner suspended or revoked under subsection (b), a provisional registration of a person under subsection (a)(1) of this section shall be in effect until—

(1) the date on which such person has registered with the Attorney General under section 303 or has had his registration denied under such section, or

(2) such date as may be prescribed by the Attorney General for registration of manufacturers, distributors, or dispensers, as the case may be,

whichever occurs first.

EFFECTIVE DATES AND OTHER TRANSITIONAL PROVISIONS

SEC. 704. [21 U.S.C. 801 note] (a) Except as otherwise provided in this section, this title shall become effective on the first day of the seventh calendar month that begins after the day immediately preceding the date of enactment.

(b) Parts A, B, E, and F of this title, section 702, this section, and sections 705 through 709, shall become effective upon enactment.

(c) Sections 305 (relating to labels and labeling), and 306 (relating to manufacturing quotas) shall become effective on the date specified in subsection (a) of this section, except that the Attorney General may by order published in the Federal Register postpone the effective date of either or both of these sections for such period as he may determine to be necessary for the efficient administration of this title.

CONTINUATION OF REGULATIONS

SEC. 705. [21 U.S.C. 801 note] Any orders, rules, and regulations which have been promulgated under any law affected by this title and which are in effect on the day preceding enactment of this title shall continue in effect until modified, superseded, or repealed.

SEVERABILITY

SEC. 706. [21 U.S.C. 901] If a provision of this Act is held invalid, all valid provisions that are severable shall remain in effect. If a provision of this Act is held invalid in one or more of its applications, the provision shall remain in effect in all its valid applications that are severable.

SAVING PROVISION

SEC. 707. [21 U.S.C. 902] Nothing in this Act, except this part and, to the extent of any inconsistency, sections 307(e) and 309 of this title, shall be construed as in any way affecting, modifying, repealing, or superseding the provisions of the Federal Food, Drug, and Cosmetic Act.

APPLICATION OF STATE LAW

SEC. 708. [21 U.S.C. 903] No provision of this title shall be construed as indicating an intent on the part of the Congress to occupy the field in which that provision operates, including criminal penalties, to the exclusion of any State law on the same subject

matter which would otherwise be within the authority of the State, unless there is a positive conflict between that provision of this title and that State law so that the two cannot consistently stand together.

PAYMENT OF TORT CLAIMS

SEC. 709. [21 U.S.C. 904] Notwithstanding section 2680(k) of title 28, United States Code, the Attorney General, in carrying out the functions of the Department of Justice under this title, is authorized to pay tort claims in the manner authorized by section 2672 of title 28, United States Code, when such claims arise in a foreign country in connection with the operations of the Drug Enforcement Administration abroad.

TITLE III—IMPORTATION AND EXPORTATION; AMENDMENTS AND REPEALS OF REVENUE LAWS

SHORT TITLE

SEC. 1000. [21 U.S.C. 951 note] This title may be cited as the "Controlled Substances Import and Export Act".

PART A—IMPORTATION AND EXPORTATION

DEFINITIONS

SEC. 1001. [21 U.S.C. 951] (a) For purposes of this part—

(1) The term "import" means, with respect to any article, any bringing in or introduction of such article into any area (whether or not such bringing in or introduction constitutes an importation within the meaning of the tariff laws of the United States).

(2) The term "customs territory of the United States" has the meaning assigned to such term by general note 2 of the Harmonized Tariff Schedule of the United States (19 U.S.C. 1202).

(b) Each term defined in section 102 of title II shall have the same meaning for purposes of this title as such term has for purposes of title II.

IMPORTATION OF CONTROLLED SUBSTANCES

SEC. 1002. [21 U.S.C. 952] (a) It shall be unlawful to import into the customs territory of the United States from any place outside thereof (but within the United States), or to import into the United States from any place outside thereof, any controlled substance in schedule I or II of title II, or ephedrine, pseudoephedrine, or phenylpropanolamine, or any narcotic drug in schedule III, IV, or V of title II, except that—

(1) such amounts of crude opium poppy straw, concentrate of poppy straw, and coca leaves, and of ephedrine, pseudoephedrine, and phenylpropanolamine, as the Attorney General finds to be necessary to provide for medical, scientific, or other legitimate purposes, and

(2) such amounts of any controlled substance in schedule I or II or any narcotic drug in schedule III, IV, or V that the

Attorney General finds to be necessary to provide for the medical, scientific, or other legitimate needs of the United States—

(A) during an emergency in which domestic supplies of such substance or drug are found by the Attorney General to be inadequate,

(B) in any case in which the Attorney General finds that competition among domestic manufacturers of the controlled substance is inadequate and will not be rendered adequate by the registration of additional manufacturers under section 303, or

(C) in any case in which the Attorney General finds that such controlled substance is in limited quantities exclusively for scientific, analytical, or research uses,

may be so imported under such regulations as the Attorney General shall prescribe. No crude opium may be so imported for the purpose of manufacturing heroin or smoking opium.

(b) It shall be unlawful to import into the customs territory of the United States from any place outside thereof (but within the United States), or to import into the United States from any place outside thereof, any nonnarcotic controlled substance in schedule III, IV, or V, unless such nonnarcotic controlled substance—

(1) is imported for medical, scientific or other legitimate uses, and

(2) is imported pursuant to such notification or declaration, or in the case of any nonnarcotic controlled substance in schedule III, such import permit, notification, or declaration, as the Attorney General may by regulation prescribe, except that if a nonnarcotic control substance in schedule IV or V is also listed in schedule I or II of the Convention on Psychotropic Substances it shall be imported pursuant to such import permit requirements, prescribed by regulation of the Attorney General, as are required by the Convention.

(c) In addition to the amount of coca leaves authorized to be imported into the United States under subsection (a), the Attorney General may permit the importation of additional amounts of coca leaves. All cocaine and ecgonine (and all salts, derivatives, and preparations from which cocaine or ecgonine may be synthesized or made) contained in such additional amounts of coca leaves imported under this subsection shall be destroyed under the supervision of an authorized representative of the Attorney General.

(d)(1) With respect to a registrant under section 1008 who is authorized under subsection (a)(1) to import ephedrine, pseudoephedrine, or phenylpropanolamine, at any time during the year the registrant may apply for an increase in the amount of such chemical that the registrant is authorized to import, and the Attorney General may approve the application if the Attorney General determines that the approval is necessary to provide for medical, scientific, or other legitimate purposes regarding the chemical.

(2) With respect to the application under paragraph (1):

(A) Not later than 60 days after receiving the application, the Attorney General shall approve or deny the application.

(B) In approving the application, the Attorney General shall specify the period of time for which the approval is in effect, or shall provide that the approval is effective until the

registrant involved is notified in writing by the Attorney General that the approval is terminated.

(C) If the Attorney General does not approve or deny the application before the expiration of the 60-day period under subparagraph (A), the application is deemed to be approved, and such approval remains in effect until the Attorney General notifies the registrant in writing that the approval is terminated.

(e) Each reference in this section to ephedrine, pseudoephedrine, or phenylpropanolamine includes each of the salts, optical isomers, and salts of optical isomers of such chemical.

EXPORTATION OF CONTROLLED SUBSTANCES

SEC. 1003. [21 U.S.C. 953] (a) It shall be unlawful to export from the United States any narcotic drug in schedule I, II, III, or IV unless—

(1) it is exported to a country which is a party to—

(A) the International Opium Convention of 1912 for the Suppression of the Abuses of Opium, Morphine, Cocaine, and Derivative Drugs, or to the International Opium Convention signed at Geneva on February 19, 1925; or

(B) the Convention for Limiting the Manufacture and Regulating the Distribution of Narcotic Drugs concluded at Geneva, July 13, 1931, as amended by the protocol signed at Lake Success on December 11, 1946, and the protocol bringing under international control drugs outside the scope of the convention of July 13, 1931, for limiting the manufacture and regulating the distribution of narcotic drugs (as amended by the protocol signed at Lake Success on December 11, 1946), signed at Paris, November 19, 1948; or

(C) the Single Convention on Narcotic Drugs, 1961, signed at New York, March 30, 1961;

(2) such country has instituted and maintains, in conformity with the conventions to which it is a party, a system for the control of imports of narcotic drugs which the Attorney General deems adequate;

(3) the narcotic drug is consigned to a holder of such permits or licenses as may be required under the laws of the country of import, and a permit or license to import such drug has been issued by the country of import;

(4) substantial evidence is furnished to the Attorney General by the exporter that (A) the narcotic drug is to be applied exclusively to medical or scientific uses within the country of import, and (B) there is an actual need for the narcotic drug for medical or scientific uses within such country; and

(5) a permit to export the narcotic drug in each instance has been issued by the Attorney General.

(b) Notwithstanding subsection (a), the Attorney General may authorize any narcotic drug (including crude opium and coca leaves) in schedule I, II, III, or IV to be exported from the United States to a country which is a party to any of the international instruments mentioned in subsection (a) if the particular drug is to

be applied to a special scientific purpose in the country of destination and the authorities of such country will permit the importation of the particular drug for such purpose.

(c) It shall be unlawful to export from the United States any nonnarcotic controlled substance in schedule I or II unless—

(1) it is exported to a country which has instituted and maintains a system which the Attorney General deems adequate for the control of imports of such substances;

(2) the controlled substance is consigned to a holder of such permits or licenses as may be required under the laws of the country of import;

(3) substantial evidence is furnished to the Attorney General that (A) the controlled substance is to be applied exclusively to medical, scientific, or other legitimate uses within the country to which exported, (B) it will not be exported from such country, and (C) there is an actual need for the controlled substance for medical, scientific, or other legitimate uses within the country; and

(4) a permit to export the controlled substance in each instance has been issued by the Attorney General.

(d) Notwithstanding subsection (c), the Attorney General may authorize any nonnarcotic controlled substance in schedule I or II to be exported from the United States if the particular substance is to be applied to a special scientific purpose in the country of destination and the authorities of such country will permit the importation of the particular drug for such purpose.

(e) It shall be unlawful to export from the United States to any other country any nonnarcotic controlled substances in schedule III or IV or any controlled substances in schedule V unless—

(1) there is furnished (before export) to the Attorney General documentary proof that importation is not contrary to the laws or regulations of the country of destination for consumption for medical, scientific, or other legitimate purposes;

(2) it is exported pursuant to such notification or declaration, or in the case of any nonnarcotic controlled substance in schedule III, such export permit, notification, or declaration as the Attorney General may by regulation prescribe; and

(3) in the case of a nonnarcotic controlled substance in schedule IV or V which is also listed in schedule I or II of the Convention on Psychotropic Substances, it is exported pursuant to such export permit requirements, prescribed by regulation of the Attorney General, as are required by the Convention.

(f) Notwithstanding subsections (a)(4) and (c)(3), the Attorney General may authorize any controlled substance that is in schedule I or II, or is a narcotic drug in schedule III or IV, to be exported from the United States to a country for subsequent export from that country to another country, if each of the following conditions is met:

(1) Both the country to which the controlled substance is exported from the United States (referred to in this subsection as the "first country") and the country to which the controlled substance is exported from the first country (referred to in this subsection as the "second country") are parties to the Single

Convention on Narcotic Drugs, 1961, and the Convention on Psychotropic Substances, 1971.

(2) The first country and the second country have each instituted and maintain, in conformity with such Conventions, a system of controls of imports of controlled substances which the Attorney General deems adequate.

(3) With respect to the first country, the controlled substance is consigned to a holder of such permits or licenses as may be required under the laws of such country, and a permit or license to import the controlled substance has been issued by the country.

(4) With respect to the second country, substantial evidence is furnished to the Attorney General by the person who will export the controlled substance from the United States that—

(A) the controlled substance is to be consigned to a holder of such permits or licenses as may be required under the laws of such country, and a permit or license to import the controlled substance is to be issued by the country; and

(B) the controlled substance is to be applied exclusively to medical, scientific, or other legitimate uses within the country.

(5)(A) The controlled substance will not be exported from the second country, except that the controlled substance may be exported from a second country that is a member of the European Economic Area to another country that is a member of the European Economic Area, provided that the first country is also a member of the European Economic Area.

(B) Subsequent to any re-exportation described in subparagraph (A), a controlled substance may continue to be exported from any country that is a member of the European Economic Area to any other such country, if—

(i) the conditions applicable with respect to the first country under paragraphs (1), (2), (3), (4), (6), and (7) are met by each subsequent country from which the controlled substance is exported pursuant to this paragraph; and

(ii) the conditions applicable with respect to the second country under paragraphs (1), (2), (3), (4), (6), and (7) are met by each subsequent country to which the controlled substance is exported pursuant to this paragraph.

(6)(A) Within 30 days after the controlled substance is exported from the first country to the second country, the person who exported the controlled substance from the United States delivers to the Attorney General documentation certifying that such export from the first country has occurred.

(B) In the case of re-exportation among members of the European Economic Area, within 30 days after each re-exportation, the person who exported the controlled substance from the United States delivers to the Attorney General—

(i) documentation certifying that such re-exportation has occurred; and

(ii) information concerning the consignee, country, and product.

(7) A permit to export the controlled substance from the United States has been issued by the Attorney General.

(g) LIMITATION.—Subject to paragraphs (5) and (6) of subsection (f) in the case of any controlled substance in schedule I or II or any narcotic drug in schedule III or IV, the Attorney General shall not promulgate nor enforce any regulation, subregulatory guidance, or enforcement policy which impedes re-exportation of any controlled substance among European Economic Area countries, including by promulgating or enforcing any requirement that—

(1) re-exportation from the first country to the second country or re-exportation from the second country to another country occur within a specified period of time; or

(2) information concerning the consignee, country, and product be provided prior to exportation of the controlled substance from the United States or prior to each re-exportation among members of the European Economic Area.

TRANSSHIPMENT AND IN-TRANSIT SHIPMENT OF CONTROLLED SUBSTANCES

SEC. 1004. [21 U.S.C. 954] Notwithstanding sections 1002, 1003, and 1007—

(1) A controlled substance in schedule I may—

(A) be imported into the United States for transshipment to another country, or

(B) be transferred or transshipped from one vessel, vehicle, or aircraft to another vessel, vehicle, or aircraft within the United States for immediate exportation,

if and only if it is so imported, transferred, or transshipped (i) for scientific, medical, or other legitimate purposes in the country of destination, and (ii) with the prior written approval of the Attorney General (which shall be granted or denied within 21 days of the request).

(2) A controlled substance in schedule II, III, or IV may be so imported, transferred, or transshipped if and only if advance notice is given to the Attorney General in accordance with regulations of the Attorney General.

POSSESSION ON BOARD VESSELS, ETC., ARRIVING IN OR DEPARTING FROM UNITED STATES

SEC. 1005. [21 U.S.C. 955] It shall be unlawful for any person to bring or possess on board any vessel or aircraft, or on board any vehicle of a carrier, arriving in or departing from the United States or the customs territory of the United States, a controlled substance in schedule I or II or a narcotic drug in schedule III or IV, unless such substance or drug is a part of the cargo entered in the manifest or part of the official supplies of the vessel, aircraft, or vehicle.

EXEMPTION AUTHORITY

SEC. 1006. [21 U.S.C. 956] (a)(1) Subject to paragraph (2), the Attorney General may by regulation exempt from sections 1002 (a) and (b), 1003, 1004, and 1005 any individual who has a controlled

substance (except a substance in schedule I) in his possession for his personal medical use, or for administration to an animal accompanying him, if the lawfully obtained such substance and he makes such declaration (or gives such other notification) as the Attorney General may by regulation require.

(2) Notwithstanding any exemption under paragraph (1), a United States resident who enters the United States through an international land border with a controlled substance (except a substance in schedule I) for which the individual does not possess a valid prescription issued by a practitioner (as defined in section 102 of the Controlled Substances Act (21 U.S.C. 802)) in accordance with applicable Federal and State law (or documentation that verifies the issuance of such a prescription to that individual) may not import the controlled substance into the United States in an amount that exceeds 50 dosage units of the controlled substance.

(b) The Attorney General may by regulation except any compound, mixture, or preparation containing any depressant or stimulant substance listed in paragraph (a) or (b) of schedule III or in schedule IV or V from the application of all or any part of this title if (1) the compound, mixture, or preparation contains one or more active medicinal ingredients not having a depressant or stimulant effect on the central nervous system, and (2) such ingredients are included therein in such combinations, quantity, proportion, or concentration as to vitiate the potential for abuse of the substances which do have a depressant or stimulant effect on the central nervous system.

PERSONS REQUIRED TO REGISTER

SEC. 1007. [21 U.S.C. 957] (a) No person may—

(1) import into the customs territory of the United States from any place outside thereof (but within the United States), or import into the United States from any place outside thereof, any controlled substance or list I chemical, or

(2) export from the United States any controlled substance or list I chemical,

unless there is in effect with respect to such person a registration issued by the Attorney General under section 1008, or unless such person is exempt from registration under subsection (b).

(b)(1) The following persons shall not be required to register under the provisions of this section and may lawfully possess a controlled substance or list I chemical:

(A) An agent or an employee of any importer or exporter registered under section 1008 if such agent or employee is acting in the usual course of his business or employment.

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

(C) An ultimate user who possesses such substance for a purpose specified in section 102(25)[67] and in conformity with an exemption granted under section 1006(a).

[67] So in law. Probably should be "102(27)". Former paragraph (25) of section 102 was redesignated as paragraph (26) by section 507(a) of Public Law 98–473 (98 Stat. 2071), and section

(2) The Attorney General may, by regulation, waive the requirement for registration of certain importers and exporters if he finds it consistent with the public health and safety; and may authorize any such importer or exporter to possess controlled substances or list I chemicals for purposes of importation and exportation.

REGISTRATION REQUIREMENTS

SEC. 1008. [21 U.S.C. 958] (a) The Attorney General shall register an applicant to import or export a controlled substance 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 section. In determining the public interest, the factors enumerated in paragraph (1) through (6) of section 303(a) shall be considered.

(b) Registration granted under this section shall not entitle a registrant to import or export controlled substances other than specified in the registration.

(c)(1) The Attorney General shall register an applicant to import a controlled substance in schedule III, IV, or V or to export a controlled substance in schedule III or IV, unless he determines that the issuance of such registration is inconsistent with the public interest. In determining the public interest, the factors enumerated in paragraphs (1) through (6) of section 303(e) shall be considered.

(2)(A) The Attorney General shall register an applicant to import or export 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 import or export of a drug product that is exempted under section 102(39)(A)(iv).

(B) In determining the public interest for the purposes of subparagraph (A), the Attorney General shall consider the factors specified in section 303(i).

(d)(1) The Attorney General may deny an application for registration under subsection (a) if he is unable to determine that such registration is consistent with the public interest (as defined in subsection (a)) and with the United States obligations under international treaties, conventions, or protocols in effect on the effective date of this part.

(2) The Attorney General may deny an application for registration under subsection (c), or revoke or suspend a registration under subsection (a) or (c), if he determines that such registration is inconsistent with the public interest (as defined in subsection (a) or (c)) or with the United States obligations under international treaties, conventions, or protocols in effect on the effective date of this part.

(3) The Attorney General may limit the revocation or suspension of a registration to the particular controlled substance, or sub-

1003(b)(2) of Public Law 99–570 (100 Stat. 3207–6) redesignated paragraph (26) as paragraph (27).

stances, or list I chemical or chemicals, with respect to which grounds for revocation or suspension exist.

(4) Before taking action pursuant to this subsection, the Attorney General shall serve upon the applicant or registrant an order to show cause as to why the 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, or his designee, 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 subsection in accordance with subchapter II of chapter 5 of title 5 of the United States Code. 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.

(5) The Attorney General may, in his discretion, suspend any registration simultaneously with the institution of proceedings under this subsection, in cases where he finds that there is an imminent danger to the public health and safety. Such suspension 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.

(6) In the event that the Attorney General suspends or revokes a registration granted under this section, all controlled substances or list I chemicals owned or possessed by the registrant pusuant 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 seized or 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 the sale thereof which have been deposited with the 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) of the Controlled Substances Act.

(e) No registration shall be issued under this part for a period in excess of one year. Unless the regulations of the Attorney General otherwise provide, sections 302(f), 305, 307, and 310 shall apply to persons registered under this section to the same extent such sections apply to persons registered under section 303.

(f)[68] The Attorney General is authorized to promulgate rules and regulations and to charge reasonable fees relating to the reg-

[68] The probable intent of the Congress was that Public Law 108–447 amend subsection (f) above. Section 633(c) of the Departments of Commerce, Justice, and State, the Judiciary, and Related Agencies Appropriations Act, 2005 (as contained in division B of Public Law 108–447; 118 Stat. 2922) provides for an amendment to section "1088(f)" of this Act, but this Act does not contain a section 1088. Section 633(c), however, also provided the citation "(21 U.S.C. 958(f))", and subsection (f) above is included in title 21, United States Code, as section 958(f).

The following shows subsection (f) as it would appear if the amendment described in section 633(c) were executed to that subsection:

istration of importers and exporters of controlled substances or list I chemicals under this section.

(g) Persons registered by the Attorney General under this section to import or export controlled substances or list I chemicals may import or export (and, for the purpose of so importing or exporting, may possess) such substances to the extent authorized by their registration and in conformity with the other provisions of this title and title II.

(h) A separate registration shall be required at each principal place of business where the applicant imports or exports controlled substances or list I chemicals.

(i) Except in emergency situations as described in section 1002(a)(2)(A), prior to issuing a registration under this section to a bulk manufacturer of a controlled substance in schedule I or II, and prior to issuing a regulation under section 1002(a) authorizing the importation of such a substance, the Attorney General shall give manufacturers holding registration for the bulk manufacture of the substance an opportunity for a hearing.

POSSESSION, MANUFACTURE OR DISTRIBUTION FOR PURPOSES OF UNLAWFUL IMPORTATION

SEC. 1009. [21 U.S.C. 959] (a) It shall be unlawful for any person to manufacture or distribute a controlled substance in schedule I or II or flunitrazepam or a listed chemical intending, knowing, or having reasonable cause to believe that such substance or chemical will be unlawfully imported into the United States or into waters within a distance of 12 miles of the coast of the United States.

(b) It shall be unlawful for any person to manufacture or distribute a listed chemical—

(1) intending or knowing that the listed chemical will be used to manufacture a controlled substance; and

(2) intending, knowing, or having reasonable cause to believe that the controlled substance will be unlawfully imported into the United States.

(c) It shall be unlawful for any United States citizen on board any aircraft, or any person on board an aircraft owned by a United States citizen or registered in United States, to—

(1) manufacture or distribute a controlled substance or listed chemical; or

(2) possess a controlled substance or listed chemical with intent to distribute.

(d)[69] This section is intended to reach acts of manufacture or distribution committed outside the territorial jurisdiction of the United States.

PROHIBITED ACTS A—PENALTIES

SEC. 1010. [21 U.S.C. 960] (a) Any person who—

"(f) The Attorney General is authorized to promulgate rules and regulations and to charge reasonable fees relating to the registration and control of importers and exporters of controlled substances or listed chemicals.".

[69] Section 1012(b)(1) of Public Law 115–91 provides for an amendment to strike "; VENUE" from the title of subsection (d). However, no such heading exists in law.

(1) contrary to section 305, 1002, 1003, or 1007, knowingly or intentionally imports or exports a controlled substance,

(2) contrary to section 1005, knowingly or intentionally brings or possesses on board a vessel, aircraft, or vehicle a controlled substance, or

(3) contrary to section 1009, manufactures, possesses with intent to distribute, or distributes a controlled substance,

shall be punished as provided in subsection (b).

(b)(1) In the case of a violation of subsection (a) of this section involving—

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

(B) 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 or 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 clauses (i) through (iii);

(C) 280 grams or more of a mixture or substance described in subparagraph (B) which contains cocaine base;

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

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

(F) 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;

(G) 1000 kilograms or more of a mixture or substance containing a detectable amount of marihuana; or

(H) 50 grams or more of methamphetamine, its salts, isomers, and salts of its isomers or 500 grams or more of a mixture or substance containing a detectable amount of methamphetamine, its salts, isomers, or salts of its isomers. [70]

the person committing such violation shall be sentenced to a term of imprisonment of not less than 10 years and not more than life 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 20 years and not 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 $10,000,000 if the defendant is an individual or $50,000,000 if the defendant is other than an individual, or both. If any person commits such a violation after a prior conviction for a serious drug felony or serious violent felony has become

[70] So in law. The period probably should be a semicolon.

final, such person shall be sentenced to a term of imprisonment of not less than 15 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 $20,000,000 if the defendant is an individual or $75,000,000 if the defendant is other than an individual, or both. Notwithstanding section 3583 of title 18[71], any sentence under this paragraph 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 paragraph. No person sentenced under this paragraph shall be eligible for parole during the term of imprisonment imposed therein.

(2) In the case of a violation of subsection (a) of this section involving—

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

(B) 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 or 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 clauses (i) through (iii);

(C) 28 grams or more of a mixture or substance described in subparagraph (B) which contains cocaine base;

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

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

(F) 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;

(G) 100 kilograms or more of a mixture or substance containing a detectable amount of marihuana; or

(H) 5 grams or more of methamphetamine, its salts, isomers, and salts of its isomers or 50 grams or more of a mixture

[71] So in law. Probably should be "title 18, United States Code". This Act does not contain a title 18.

or substance containing a detectable amount of methamphetamine, its salts, isomers, or salts of its isomers. [72]

the person committing such violation shall be sentenced to a term of imprisonment of not 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 sentenced to a term of imprisonment of not less than twenty years and not 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 $5,000,000 if the defendant is an individual or $25,000,000 if the defendant is other than an individual, or both. If any person commits such a violation after a prior conviction for a serious drug felony or serious violent felony has become final, such person shall be sentenced to a term of imprisonment of not 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 $8,000,000 if the defendant is an individual or $50,000,000 if the defendant is other than an individual, or both. Notwithstanding section 3583 of title 18 [73], any sentence imposed under this paragraph 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 paragraph. No person sentenced under this paragraph shall be eligible for parole during the term of imprisonment imposed therein.

(3) In the case of a violation under subsection (a) of this section involving a controlled substance in schedule I or II, gamma hydroxybutyric acid (including when scheduled as an approved drug product for purposes of section 3(a)(1)(B) of the Hillory J. Farias and Samantha Reid Date-Rape Drug Prohibition Act of 2000), or flunitrazepam, the person committing such violation shall, except as provided in paragraphs (1), (2), and (4), 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 and not 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

[72] So in law. The period probably should be a semicolon.

[73] So in law. Probably should be "title 18, United States Code". This Act does not contain a title 18.

or $10,000,000 if the defendant is other than an individual, or both. Notwithstanding section 3583 of title 18[74], any sentence imposing a term of imprisonment under this paragraph shall, in the absence of such a prior conviction, impose a term of suspervised 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 suspervised release of at least 6 years in addition to such term of imprisonment. Notwithstanding the prior sentence, and 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 paragraph which provide for a mandatory term of imprisonment if death or serious bodily injury results.

(4) In the case of a violation under subsection (a) with respect to less than 50 kilograms of marihuana except in the case of 100 or more marihuana plants regardless of weight, less than 10 kilograms of hashish, or less than one kilogram of hashish oil, the person committing such violation shall be sentenced in accordance with section 401(b)(1)(D).

(5) In the case of a violation of subsection (a) involving a controlled substance in schedule III, such person shall be sentenced in accordance with section 401(b)(1).

(6) In the case of a violation of subsection (a) involving a controlled substance in schedule IV, such person shall be sentenced in accordance with section 401(b)(2).

(7) In the case of a violation of subsection (a) involving a controlled substance in schedule V, such person shall be sentenced in accordance with section 401(b)(3).

(c)[75] A special parole term imposed under this section or section 1012 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 special parole term and the resulting new term of imprisonment shall not be diminished by the time which was spent on special parole. A person whose special parole term has been revoked may be required to serve all or part of the remainder of the new term of imprisonment. The special term provided for in this section and in section 1012 is in addition to, and not in lieu of, any other parole provided for by law.

(d) A person who knowingly or intentionally—

(1) imports or exports a listed chemical with intent to manufacture a controlled substance in violation of this title or title II;

(2) exports a listed chemical in violation of the laws of the country to which the chemical is exported or serves as a broker or trader for an international transaction involving a listed

[74] So in law. Probably should be "title 18, United States Code". This Act does not contain a title 18.

[75] The probable intent of the Congress is that subsection (c) not appear in the law. Section 225 of Public Law 98–473 (98 Stat. 2030) provided that section 1010 above is amended "by repealing subsection (c)". That repeal, however, was subject to a delayed effective date (see section 235 of such Public Law), and before that effective date was reached, section 1005(c) of Public Law 99–570 (100 Stat. 3207–6) amended section 225 of Public Law 98–473 so that the text of section 225 provided as follows: "Section 1515 of the Controlled Substances Import and Export Act (21 U.S.C. 960) is amended by repealing subsection (c).". The probable intent of the Congress was that the amended section 225 strike subsection (c) of section 1010, not section 1515, as this Act does not contain a section 1515 and as the cite provided to the United States Code is the Code citation for section 1010.

chemical, if the transaction is in violation of the laws of the country to which the chemical is exported;

(3) imports or exports a listed chemical knowing, or having reasonable cause to believe, that the chemical will be used to manufacture a controlled substance in violation of this title or title II;

(4) exports a listed chemical, or serves as a broker or trader for an international transaction involving a listed chemical, knowing, or having reasonable cause to believe, that the chemical will be used to manufacture a controlled substance in violation of the laws of the country to which the chemical is exported;

(5) imports or exports a listed chemical, with the intent to evade the reporting or recordkeeping requirements of section 1018 applicable to such importation or exportation by falsely representing to the Attorney General that the importation or exportation qualifies for a waiver of the 15-day notification requirement granted pursuant to paragraph (2) or (3) of section 1018(f) by misrepresenting the actual country of final destination of the listed chemical or the actual listed chemical being imported or exported;

(6) imports a listed chemical in violation of section 1002, imports or exports such a chemical in violation of section 1007 or 1018, or transfers such a chemical in violation of section 1018(d); or

(7) manufactures, possesses with intent to distribute, or distributes a listed chemical in violation of section 959 of this title.[76]

shall be fined in accordance with title 18, imprisoned not more than 20 years in the case of a violation of paragraph (1) or (3) involving a list I chemical or not more than 10 years in the case of a violation of this subsection other than a violation of paragraph (1) or (3) involving a list I chemical, or both.

FOREIGN TERRORIST ORGANIZATIONS, TERRORIST PERSONS AND GROUPS

Prohibited Acts

SEC. 1010A. [21 U.S.C. 960a] (a) Whoever engages in conduct that would be punishable under section 841(a) of this title if committed within the jurisdiction of the United States, or attempts or conspires to do so, knowing or intending to provide, directly or indirectly, anything of pecuniary value to any person or organization that has engaged or engages in terrorist activity (as defined in section 212(a)(3)(B) of the Immigration and Nationality Act) or terrorism (as defined in section 140(d)(2) of the Foreign Relations Authorization Act, Fiscal Years 1988 and 1989), shall be sentenced to a term of imprisonment of not less than twice the minimum punishment under section 841(b)(1), and not more than life, a fine in accordance with the provisions of title 18, United States Code, or both. Notwithstanding section 3583 of title 18, United States Code,

[76] The reference to section 959 is so in law. See 102(c)(3) of Public Law 104–237 (110 Stat. 3100). Probably should be a reference to section 1009.

any sentence imposed under this subsection shall include a term of supervised release of at least 5 years in addition to such term of imprisonment.

Jurisdiction

(b) There is jurisdiction over an offense under this section if—

(1) the prohibited drug activity or the terrorist offense is in violation of the criminal laws of the United States;

(2) the offense, the prohibited drug activity, or the terrorist offense occurs in or affects interstate or foreign commerce;

(3) an offender provides anything of pecuniary value for a terrorist offense that causes or is designed to cause death or serious bodily injury to a national of the United States while that national is outside the United States, or substantial damage to the property of a legal entity organized under the laws of the United States (including any of its States, districts, commonwealths, territories, or possessions) while that property is outside of the United States;

(4) the offense or the prohibited drug activity occurs in whole or in part outside of the United States (including on the high seas), and a perpetrator of the offense or the prohibited drug activity is a national of the United States or a legal entity organized under the laws of the United States (including any of its States, districts, commonwealths, territories, or possessions); or

(5) after the conduct required for the offense occurs an offender is brought into or found in the United States, even if the conduct required for the offense occurs outside the United States.

Proof Requirements

(c) To violate subsection (a), a person must have knowledge that the person or organization has engaged or engages in terrorist activity (as defined in section 212(a)(3)(B) of the Immigration and Nationality Act) or terrorism (as defined in section 140(d)(2) of the Foreign Relations Authorization Act, Fiscal Years 1988 and 1989).

Definition

(d) As used in this section, the term "anything of pecuniary value" has the meaning given the term in section 1958(b)(1) of title 18, United States Code.

PROHIBITED ACTS B—PENALTIES

SEC. 1011. [21 U.S.C. 961] Any person who violates section 1004 or fails to notify the Attorney General of an importation or exportation under section 1018 shall be subject to the following penalties:

(1) Except as provided in paragraph (2), any such person shall, with respect to any such violation, be subject to a civil penalty of not more than $25,000. Sections 402(c)(1) and (c)(3) shall apply to any civil penalty assessed under this paragraph.

(2) If such a violation is prosecuted by an information or indictment which alleges that the violation was committed knowingly or intentionally and the trier of fact specifically finds that the violation was so committed, such person shall be sentenced to imprisonment for not more than one year or a fine of not more than $25,000 or both.

SECOND OR SUBSEQUENT OFFENSES

SEC. 1012. [21 U.S.C. 962] (a) Any person convicted of any offense under this part is, if the offense is a second or subsequent offense, punishable by a term of imprisonment twice that otherwise authorized, by twice the fine otherwise authorized, or by both.

(b) For purposes of this section, a person shall be considered convicted of a second or subsequent offense if, prior to the commission of such offense, one or more prior convictions of such person for a felony drug offense have become final.

(c) Section 411 shall apply with respect to any proceeding to sentence a person under this section.

ATTEMPT AND CONSPIRACY

SEC. 1013. [21 U.S.C. 963] 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.

ADDITIONAL PENALTIES

SEC. 1014. [21 U.S.C. 964] 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.

APPLICABILITY OF PART E OF TITLE II

SEC. 1015. [21 U.S.C. 965] Part E of title II shall apply with respect to functions of the Attorney General (and of officers and employees of the Bureau of Narcotics and Dangerous Drugs) under this title, to administrative and judicial proceedings under this title, and to violations of this title, to the same extent that such part applies to functions of the Attorney General (and such officers and employees) under title II, to such proceedings under title II, and to violations of title II. For purposes of the application of this section to section 510 or 511, any reference in such section 510 or 511 to "this title" shall be deemed to be a reference to title III, any reference to section 303 shall be deemed to be a reference to section 1008, and any reference to section 302(d) shall be deemed to be a reference to section 1007(b)(2).

AUTHORITY OF SECRETARY OF TREASURY

SEC. 1016. [21 U.S.C. 966] Nothing in this Act shall derogate from the authority of the Secretary of the Treasury under the customs and related laws.

CRIMINAL FORFEITURES

SEC. 1017. [21 U.S.C. 970] Section 413 of title II, relating to criminal forfeitures, shall apply in every respect to a violation of this title punishable by imprisonment for more than one year.

NOTIFICATION, SUSPENSION OF SHIPMENT, AND PENALTIES WITH RESPECT TO IMPORTATION AND EXPORTATION OF LISTED CHEMICALS

SEC. 1018. [21 U.S.C. 971] (a) Each regulated person who imports or exports a listed chemical shall notify the Attorney General of the importation or exportation not later than 15 days before the transaction is to take place.

(b)(1) The Attorney General shall provide by regulation for circumstances in which the requirement of subsection (a) does not apply to a transaction between a regulated person and a regular customer or to a transaction that is an importation by a regular importer. At the time of any importation or exportation constituting a transaction referred to in the preceding sentence, the regulated person shall notify the Attorney General of the transaction.

(2) The regulations under this subsection shall provide that the initial notification under subsection (a) with respect to a customer of a regulated person or to an importer shall, upon the expiration of the 15-day period, qualify the customer as a regular customer or the importer as a regular importer, unless the Attorney General otherwise notifies the regulated person in writing.

(c)(1) The Attorney General may order the suspension of any importation or exportation of a listed chemical (other than a regulated transaction to which the requirement of subsection (a) does not apply by reason of subsection (b)) or may disqualify any regular customer or regular importer on the ground that the chemical may be diverted to the clandestine manufacture of a controlled substance (without regard to the form of the chemical that may be diverted, including the diversion of a finished drug product to be manufactured from bulk chemicals to be transferred). From and after the time when the Attorney General provides written notice of the order (including a statement of the legal and factual basis for the order) to the regulated person, the regulated person may not carry out the transaction.

(2) Upon written request to the Attorney General, a regulated person to whom an order applies under paragraph (1) is entitled to an agency hearing on the record in accordance with subchapter II of chapter 5 of title 5, United States Code. The hearing shall be held on an expedited basis and not later than 45 days after the request is made, except that the hearing may be held at a later time, if so requested by the regulated person.

(d)(1)(A) Information provided in a notice under subsection (a) or (b) shall include the name of the person to whom the importer or exporter involved intends to transfer the listed chemical involved, and the quantity of such chemical to be transferred.

(B) In the case of a notice under subsection (b) submitted by a regular importer, if the transferee identified in the notice is not a regular customer, such importer may not transfer the listed chemical until after the expiration of the 15-day period beginning

on the date on which the notice is submitted to the Attorney General.

(C) After a notice under subsection (a) or (b) is submitted to the Attorney General, if circumstances change and the importer or exporter will not be transferring the listed chemical to the transferee identified in the notice, or will be transferring a greater quantity of the chemical than specified in the notice, the importer or exporter shall update the notice to identify the most recent prospective transferee or the most recent quantity or both (as the case may be) and may not transfer the listed chemical until after the expiration of the 15-day period beginning on the date on which the update is submitted to the Attorney General, except that such 15-day restriction does not apply if the prospective transferee identified in the update is a regular customer. The preceding sentence applies with respect to changing circumstances regarding a transferee or quantity identified in an update to the same extent and in the same manner as such sentence applies with respect to changing circumstances regarding a transferee or quantity identified in the original notice under subsection (a) or (b).

(D) In the case of a transfer of a listed chemical that is subject to a 15-day restriction under subparagraph (B) or (C), the transferee involved shall, upon the expiration of the 15-day period, be considered to qualify as a regular customer, unless the Attorney General otherwise notifies the importer or exporter involved in writing.

(2) With respect to a transfer of a listed chemical with which a notice or update referred to in paragraph (1) is concerned:

(A) The Attorney General, in accordance with the same procedures as apply under subsection (c)(2)—

(i) may order the suspension of the transfer of the listed chemical by the importer or exporter involved, except for a transfer to a regular customer, on the ground that the chemical may be diverted to the clandestine manufacture of a controlled substance (without regard to the form of the chemical that may be diverted, including the diversion of a finished drug product to be manufactured from bulk chemicals to be transferred), subject to the Attorney General ordering such suspension before the expiration of the 15-day period referred to in paragraph (1) with respect to the importation or exportation (in any case in which such a period applies); and

(ii) may, for purposes of clause (i) and paragraph (1), disqualify a regular customer on such ground.

(B) From and after the time when the Attorney General provides written notice of the order under subparagraph (A) (including a statement of the legal and factual basis for the order) to the importer or exporter, the importer or exporter may not carry out the transfer.

(3) For purposes of this subsection:

(A) The terms "importer" and "exporter" mean a regulated person who imports or exports a listed chemical, respectively.

(B) The term "transfer", with respect to a listed chemical, includes the sale of the chemical.

(C) The term "transferee" means a person to whom an importer or exporter transfers a listed chemical.

(e) A person located in the United States who is a broker or trader for an international transaction in a listed chemical that is a regulated transaction solely because of that person's involvement as a broker or trader shall, with respect to that transaction, be subject to all of the notification, reporting, recordkeeping, and other requirements placed upon exporters of listed chemicals by this title and title II.

(f)(1) The Attorney General may by regulation require that the 15-day notification requirement of subsection (a) apply to all exports of a listed chemical to a specified country, regardless of the status of certain customers in such country as regular customers, if the Attorney General finds that such notification is necessary to support effective chemical diversion control programs or is required by treaty or other international agreement to which the United States is a party.

(2) The Attorney General may by regulation waive the 15-day notification requirement for exports of a listed chemical to a specified country if the Attorney General determines that such notification is not required for effective chemical diversion control. If the notification requirement is waived, exporters of the listed chemical shall be required to submit to the Attorney General reports of individual exportations or periodic reports of such exportation of the listed chemical, at such time or times and containing such information as the Attorney General shall establish by regulation.

(3) The Attorney General may by regulation waive the 15-day notification requirement for the importation of a listed chemical if the Attorney General determines that such notification is not necessary for effective chemical diversion control. If the notification requirement is waived, importers of the listed chemical shall be required to submit to the Attorney General reports of individual importations or periodic reports of the importation of the listed chemical, at such time or times and containing such information as the Attorney General shall establish by regulation.

(g) Within 30 days after a transaction covered by this section is completed, the importer or exporter shall send the Attorney General a return declaration containing particulars of the transaction, including the date, quantity, chemical, container, name of transferees, and such other information as the Attorney General may specify in regulations. For importers, a single return declaration may include the particulars of both the importation and distribution. If the importer has not distributed all chemicals imported by the end of the initial 30-day period, the importer shall file supplemental return declarations no later than 30 days from the date of any further distribution, until the distribution or other disposition of all chemicals imported pursuant to the import notification or any update are accounted for.

(h)(1) With respect to a regulated person importing ephedrine, pseudoephedrine, or phenylpropanolamine (referred to in this section as an "importer"), a notice of importation under subsection (a) or (b) shall include all information known to the importer on the chain of distribution of such chemical from the manufacturer to the importer.

(2) For the purpose of preventing or responding to the diversion of ephedrine, pseudoephedrine, or phenylpropanolamine for use in the illicit production of methamphetamine, the Attorney General may, in the case of any person who is a manufacturer or distributor of such chemical in the chain of distribution referred to in paragraph (1) (which person is referred to in this subsection as a "foreign-chain distributor"), request that such distributor provide to the Attorney General information known to the distributor on the distribution of the chemical, including sales.

(3) If the Attorney General determines that a foreign-chain distributor is refusing to cooperate with the Attorney General in obtaining the information referred to in paragraph (2), the Attorney General may, in accordance with procedures that apply under subsection (c), issue an order prohibiting the importation of ephedrine, pseudoephedrine, or phenylpropanolamine in any case in which such distributor is part of the chain of distribution for such chemical. Not later than 60 days prior to issuing the order, the Attorney General shall publish in the Federal Register a notice of intent to issue the order. During such 60-day period, imports of the chemical with respect to such distributor may not be restricted under this paragraph.

PART B—AMENDMENTS AND REPEALS, TRANSITIONAL AND EFFECTIVE DATE PROVISIONS [77]

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[77] Part B consists of sections 1101–1105. Such sections are omitted from this compilation. For text of sections 1101–1102, see 84 Stat. 1291, 1292. For text of sections 1103–1105 (84 Stat. 1294–1295), see notes for 21 U.S.C. 171, 957, and 951, respectively.