



KeyCite Yellow Flag - Negative Treatment

Unconstitutional or Preempted Prior Version Held Unconstitutional as Applied by [U.S. v. Roberts](#), S.D.N.Y., Sep. 09, 2002



KeyCite Yellow Flag - Negative Treatment

Proposed Legislation

United States Code Annotated

Title 21. Food and Drugs (Refs & Annos)

Chapter 13. Drug Abuse Prevention and Control (Refs & Annos)

Subchapter I. Control and Enforcement

Part A. Introductory Provisions (Refs & Annos)

21 U.S.C.A. § 802

§ 802. Definitions

Effective: December 21, 2018

[Currentness](#)

As used in this subchapter:

- (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 subchapter, 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 subchapter. 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 1986.

(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 321\(g\)\(1\)](#) of this title.

(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 term “marihuana” means all parts of the plant *Cannabis sativa* L., whether growing or not; the seeds thereof; the resin extracted from any part of such plant; and every compound, manufacture, salt, derivative, mixture, or preparation of such plant, its seeds or resin.

(B) The term “marihuana” does not include--

(i) hemp, as defined in [section 1639o of Title 7](#); 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, ethers, salts, and salts of isomers, esters, and ethers, whenever the existence of such isomers, esters, ethers, and salts is possible within the specific chemical designation. Such term does not include the isoquinoline alkaloids of opium.

(B) Poppy straw and concentrate of poppy straw.

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

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

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

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

(18) The term “opiate” 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, organ, or mental faculty.

(26) 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.

(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 355](#) of this title to the extent conduct with respect to such substance is pursuant to such exemption; or

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

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

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

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

(B) Benzyl cyanide.

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

(D) Ergonovine and its salts.

(E) Ergotamine and its salts.

(F) N-Acetylanthranilic acid, its esters, and its salts.

(G) Norpseudoephedrine, its salts, optical isomers, and salts of optical isomers.

(H) Phenylacetic acid, its esters, and its salts.

(I) Phenylpropanolamine, its salts, optical isomers, and salts of optical isomers.

(J) Piperidine and its salts.

(K) Pseudoephedrine, its salts, optical isomers, and salts of optical isomers.

(L) 3,4-Methylenedioxyphenyl-2-propanone.

(M) Methylamine.

(N) Ethylamine.

(O) Propionic anhydride.

(P) Isosafrole.

(Q) Safrole.

(R) Piperonal.

(S) N-Methylephedrine.

(T) N-methylpseudoephedrine.

(U) Hydriodic acid.

(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 subchapter, and such term includes (until otherwise specified by regulation of the Attorney General, as considered appropriate by the Attorney General or upon petition to the Attorney General by any person) the following chemicals:

(A) Acetic anhydride.

(B) Acetone.

(C) Benzyl chloride.

(D) Ethyl ether.

(E) Repealed. Pub.L. 101-647, Title XXIII, § 2301(b), Nov. 29, 1990, 104 Stat. 4858.

(F) Potassium permanganate.

(G) 2-Butanone (or Methyl Ethyl Ketone).

(H) Toluene.

(I) Iodine.

(J) Hydrochloric gas.

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

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

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

(39) The term “regulated transaction” means--

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

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

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

(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 subchapter or subchapter II;

(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 814](#) of this title 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 830\(b\)\(3\)](#) of this title; or

(vi) any transaction in a chemical mixture which the Attorney General has by regulation designated as exempt from the application of this subchapter and subchapter II 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) androstenediol--

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

- (II) 3 α ,17 β -dihydroxy-5 α - androstane;
- (ii) androstanedione (5 α -androstan-3,17-dione);
- (iii) androstenediol--
 - (I) 1-androstenediol (3 β ,17 β -dihydroxy-5 α -androst-1-ene);
 - (II) 1-androstenediol (3 α ,17 β -dihydroxy-5 α -androst-1-ene);
 - (III) 4-androstenediol (3 β ,17 β -dihydroxy-androst-4-ene); and
 - (IV) 5-androstenediol (3 β ,17 β -dihydroxy-androst-5-ene);
- (iv) androstenedione--
 - (I) 1-androstenedione ([5 α]-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 (7 α ,17 α - dimethyl-17 β -hydroxyandrost-4-en-3-one);
- (vi) boldenone (17 β -hydroxyandrost-1,4,-diene-3-one);
- (vii) calusterone (7 β , 17 α -dimethyl-17 β -hydroxyandrost-4-en-3-one);
- (viii) clostebol (4-chloro-17 β -hydroxyandrost-4-en-3-one);
- (ix) dehydrochloromethyltestosterone (4-chloro-17 β -hydroxy-17 α -methyl-androst-1, 4-dien-3-one);
- (x) Δ 1-dihydrotestosterone (a.k.a. “1-testosterone”) (17 β -hydroxy-5 α -androst-1-en-3-one);
- (xi) 4-dihydrotestosterone (17 β -hydroxy-androstan-3-one);

- (xii) drostanolone (17 β -hydroxy-2 α -methyl-5 α -androstan-3-one);
- (xiii) ethylestrenol (17 α -ethyl-17 β -hydroxyestr-4-ene);
- (xiv) fluoxymesterone (9-fluoro-17 α -methyl-11 β , 17 β -dihydroxyandrost-4-en-3-one);
- (xv) formebolone (2-formyl-17 α -methyl-11 α , 17 β -dihydroxyandrost-1,4-dien-3-one);
- (xvi) furazabol (17 α -methyl-17 β -hydroxyandrostan[2,3-c]-furan);
- (xvii) 13 β -ethyl-17 β -hydroxygon-4-en-3-one;
- (xviii) 4-hydroxytestosterone (4,17 β -dihydroxy-androst-4-en-3-one);
- (xix) 4-hydroxy-19-nortestosterone (4,17 β -dihydroxy-estr-4-en-3-one);
- (xx) mestanolone (17 α -methyl-17 β -hydroxy-5 α -androstan-3-one);
- (xxi) mesterolone (1 α -methyl-17 β -hydroxy-[5 α]-androstan-3-one);
- (xxii) methandienone (17 α -methyl-17 β -hydroxyandrost-1,4-dien-3-one);
- (xxiii) methandriol (17 α -methyl-3 β ,17 β -dihydroxyandrost-5-ene);
- (xxiv) methenolone (1-methyl-17 β -hydroxy-5 α -androst-1-en-3-one);
- (xxv) 17 α -methyl-3 β , 17 β -dihydroxy-5 α -androstane;
- (xxvi) 17 α -methyl-3 α , 17 β -dihydroxy-5 α -androstane;
- (xxvii) 17 α -methyl-3 β , 17 β -dihydroxyandrost-4-ene.
- (xxviii) 17 α -methyl-4-hydroxynandrolone (17 α -methyl-4-hydroxy-17 β -hydroxyestr-4-en-3-one);
- (xxix) methyldienolone (17 α -methyl-17 β -hydroxyestra-4,9(10)-dien-3-one);

(xxx) methyltrienolone (17 α -methyl-17 β -hydroxyestra-4,9-11-trien-3-one);

(xxxi) methyltestosterone (17 α -methyl-17 β -hydroxyandrost-4-en-3-one);

(xxxii) mibolerone (7 α , 17 α -dimethyl-17 β -hydroxyestr-4-en-3-one);

(xxxiii) 17 α -methyl- Δ 1-dihydrotestosterone (17 β -hydroxy-17 α -methyl-5 α - androst-1-en-3-one) (a.k.a. “17- α -methyl-1-testosterone”);

(xxxiv) nandrolone (17 β -hydroxyestr-4-en-3-one);

(xxxv) norandrostenediol--

(I) 19-nor-4-androstenediol (3 β , 17 β -dihydroxyestr-4-ene);

(II) 19-nor-4-androstenediol (3 α , 17 β -dihydroxyestr-4-ene);

(III) 19-nor-5-androstenediol (3 β , 17 β -dihydroxyestr-5-ene); and

(IV) 19-nor-5-androstenediol (3 α , 17 β -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 (13 β , 17 α -diethyl-17 β -hydroxygon-4-en-3-one);

(xxxviii) norclostebol (4-chloro-17 β -hydroxyestr-4-en-3-one);

(xxxix) norethandrolone (17 α -ethyl-17 β -hydroxyestr-4-en-3-one);

(xl) normethandrolone (17 α -methyl-17 β -hydroxyestr-4-en-3-one);

(xli) oxandrolone (17 α -methyl-17 β -hydroxy-2-oxa-[5 α]- androstan-3-one);

- (xlii) oxymesterone (17 α -methyl-4,17 β -dihydroxyandrost-4-en-3-one);
- (xliii) oxymetholone (17 α -methyl-2-hydroxymethylene-17 β -hydroxy- [5 α]-androstan-3-one);
- (xliv) stanozolol (17 α -methyl- 17 β -hydroxy-[5 α]-androst-2-eno[3,2-c]-pyrazole);
- (xlv) stenbolone (17 β -hydroxy-2-methyl-[5 α] -androst-1-en-3-one);
- (xlvi) testolactone (13-hydroxy-3-oxo-13,17-secoandrosta-1,4-dien-17-oic acid lactone);
- (xlvii) testosterone (17 β -hydroxyandrost-4-en-3-one);
- (xlviii) tetrahydrogestrinone (13 β ,17 α -diethyl-17 β -hydroxygon-4,9, 11-trien-3-one);
- (xlix) trenbolone (17 β -hydroxyestr-4,9,11-trien-3-one);
- (l) 5 α -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-17 α -methyl-androsta-1,4-diene-3,17 β -diol;
- (liv) 4-chloro-17 α -methyl-androst-4-ene-3 β ,17 β -diol;
- (lv) 4-chloro-17 α -methyl-17 β -hydroxy-androst-4-en-3-one;
- (lvi) 4-chloro-17 α -methyl-17 β -hydroxy-androst-4-ene-3,11-dione;
- (lvii) 4-chloro-17 α -methyl-androsta-1,4-diene-3,17 β -diol;
- (lviii) 2 α ,17 α -dimethyl-17 β -hydroxy-5 α -androstan-3-one;
- (lix) 2 α ,17 α -dimethyl-17 β -hydroxy-5 β -androstan-3-one;

- (lx) 2 α ,3 α -epithio-17 α -methyl-5 α -androstan-17 β -ol;
- (lxi) [3,2-c]-furazan-5 α -androstan-17 β -ol;
- (lxii) 3 β -hydroxy-estra-4,9,11-trien-17-one;
- (lxiii) 17 α -methyl-androst-2-ene-3,17 β -diol;
- (lxiv) 17 α -methyl-androsta-1,4-diene-3,17 β -diol;
- (lxv) Estra-4,9,11-triene-3,17-dione;
- (lxvi) 18a-Homo-3-hydroxy-estra-2,5(10)-dien-17-one;
- (lxvii) 6 α -Methyl-androst-4-ene-3,17-dione;
- (lxviii) 17 α -Methyl-androstan-3-hydroxyimine-17 β -ol;
- (lxix) 17 α -Methyl-5 α -androstan-17 β -ol;
- (lxx) 17 β -Hydroxy-androstano[2,3-d]isoxazole;
- (lxxi) 17 β -Hydroxy-androstano[3,2-c]isoxazole;
- (lxxii) 4-Hydroxy-androst-4-ene-3,17-dione[3,2-c]pyrazole-5 α -androstan-17 β -ol;
- (lxxiii) [3,2-c]pyrazole-androst-4-en-17 β -ol;
- (lxxiv) [3,2-c]pyrazole-5 α -androstan-17 β -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 811](#) of this title.

(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 chapter 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 885\(a\)](#) of this title, 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) 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 811\(a\)](#) of this title added to any of the schedules under [section 812\(c\)](#) of this title. 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 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) 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 \(a\), \(b\), \(d\), or \(e\) of section 823](#) of this title who do not dispense controlled substances to an unregistered individual or entity;

(ii) nonpharmacy practitioners who are registered under [section 823\(f\)](#) of this title 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 823\(f\)](#) of this title;

(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;

(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 823\(f\)](#) of this title 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 subchapter, 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 1395m\(m\) of Title 42](#), 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 823\(f\)](#) of this title; 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 823\(f\)](#) of this title in the State in which the patient is located, unless the practitioner--

(aa) is exempted from such registration in all States under [section 822\(d\)](#) of this title; 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 823\(f\)](#) of this title in any State or is utilizing the registration of a hospital or clinic operated by the Department of Veterans Affairs registered under [section 823\(f\)](#) of this title;

(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 823\(f\)](#) of this title in the State in which the patient is located, unless the practitioner--

(I) is exempted from such registration in all States under [section 822\(d\)](#) of this title; 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 823\(f\)](#) of this title in any State or is using the registration of a hospital or clinic operated by the Department of Veterans Affairs registered under [section 823\(f\)](#) of this title;

(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 831\(g\)\(2\)](#) of this title;

(D)(i) is being conducted during a public health emergency declared by the Secretary under [section 247d of Title 42](#); 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;

(E) is being conducted by a practitioner who has obtained from the Attorney General a special registration under [section 831\(h\)](#) of this title;

(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 823\(f\)](#) of this title 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 823\(f\)](#) of this title;

(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 823\(f\)](#) of this title in any State or is utilizing the registration of a hospital or clinic operated by the Department of Veterans Affairs registered under [section 823\(f\)](#) of this title; 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 829](#) of this title, 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 829](#) of this title (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 determine 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) ¹ 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) ¹ The term “serious drug felony” means an offense described in [section 924\(e\)\(2\) of Title 18](#) 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](#) 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](#), 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.

CREDIT(S)

(Pub.L. 91-513, Title II, § 102, Oct. 27, 1970, 84 Stat. 1242; Pub.L. 93-281, § 2, May 14, 1974, 88 Stat. 124; Pub.L. 95-633, Title I, § 102(b), Nov. 10, 1978, 92 Stat. 3772; Pub.L. 96-132, § 16(a), Nov. 30, 1979, 93 Stat. 1049; Pub.L. 98-473, Title II, § 507(a), (b), Oct. 12, 1984, 98 Stat. 2071; Pub.L. 98-509, Title III, § 301(a), Oct. 19, 1984, 98 Stat. 2364; Pub.L. 99-514, § 2, Oct. 22, 1986, 100 Stat. 2095; Pub.L. 99-570, Title I, §§ 1003(b), 1203, 1870, Oct. 27, 1986, 100 Stat. 3207-6, 3207-13, 3207-56; Pub.L. 99-646, § 83, Nov. 10, 1986, 100 Stat. 3619; Pub.L. 100-690, Title VI, § 6054, Nov. 18, 1988, 102 Stat. 4316; Pub.L. 101-647, Title XIX, § 1902(b), Title XXIII, § 2301, Title XXXV, § 3599I, Nov. 29, 1990, 104 Stat. 4852, 4858, 4932; Pub.L. 103-200, §§ 2(a), 7 to 9(a), Dec. 17, 1993, 107 Stat. 2333, 2340; Pub.L. 103-322, Title IX, § 90105(d), Title XXXIII, § 330024(a), (b), (d)(1), Sept. 13, 1994, 108 Stat. 1988, 2150; Pub.L. 104-237, Title II, §§ 204(a), 209, Title IV, § 401(a), (b), Oct. 3, 1996, 110 Stat. 3102, 3104, 3106, 3107; Pub.L. 104-294, Title VI, §§ 604(b)(4), 607(j), Oct. 11, 1996, 110 Stat. 3506, 3512; Pub.L. 105-115, Title I, § 126(c)(3), Nov. 21, 1997, 111 Stat. 2328; Pub.L. 106-172, §§ 3(c), 5(a), Feb. 18, 2000, 114 Stat. 9, 10; Pub.L. 106-310, Div. B, Title XXXVI, § 3622(a), Oct. 17, 2000, 114 Stat. 1231; Pub.L. 107-273, Div. B, Title IV, § 4002(c)(1), Nov. 2, 2002, 116 Stat. 1808; Pub.L. 108-358, § 2(a), Oct. 22, 2004, 118 Stat. 1661; Pub.L. 109-162, Title XI, § 1180, Jan. 5, 2006, 119 Stat. 3126; Pub.L. 109-177, Title VII, §§ 711(a)(1), (2)(A), 712(a)(1), Mar. 9, 2006, 120 Stat. 256, 257, 263; Pub.L. 110-425, § 3(a), Oct. 15, 2008, 122 Stat. 4821; Pub.L. 113-260, § 2(a), Dec. 18, 2014, 128 Stat. 2929; Pub.L. 114-198, Title III, § 303(a)(2), July 22, 2016, 130 Stat. 722; Pub.L. 115-271, Title III, §§ 3202(c), 3292(a), Oct. 24, 2018, 132 Stat. 3945, 3956; Pub.L. 115-334, Title XII, § 12619(a), Dec. 20, 2018, 132 Stat. 5018; Pub.L. 115-391, Title IV, § 401(a)(1), Dec. 21, 2018, 132 Stat. 5220.)

Notes of Decisions (152)

Footnotes

¹ So in original. Two pars. (57) have been enacted.

21 U.S.C.A. § 802, 21 USCA § 802

Current through P.L. 117-179. Some statute sections may be more current, see credits for details.

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