115TH CONGRESS
2d Session
HOUSE OF REPRESENTATIVES
REPT. 115–713
Part 1

STOP THE IMPORTATION AND TRAFFICKING OF SYNTHETIC ANALOGUES ACT OF 2017

JUNE 8, 2018.—Ordered to be printed

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

R E P O R T

together with

DISSENTING VIEWS

[To accompany H.R. 2851]

[Including cost estimate of the Congressional Budget Office]

The Committee on the Judiciary, to whom was referred the bill (H.R. 2851) to amend the Controlled Substances Act to clarify how controlled substance analogues are to be regulated, and for other purposes, having considered the same, report favorably thereon with an amendment and recommend that the bill as amended do pass.

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79–006

The Amendment

The amendment is as follows:

Strike all that follows after the enacting clause, and insert the following:

SECTION 1. SHORT TITLE.

This Act may be cited as the "Stop the Importation and Trafficking of Synthetic Analogues Act of 2017" or the "SITSA Act".

SEC. 2. ESTABLISHMENT OF SCHEDULE A.

Section 202 of the Controlled Substances Act (21 U.S.C. 812) is amended—

(1) in subsection (a), by striking "five schedules of controlled substances, to be known as schedules I, II, III, IV, and V" and inserting "six schedules of controlled substances, to be known as schedules I, II, III, IV, V, and A";

(2) in subsection (b), by adding at the end the following:

"(6) SCHEDULE A.—

"(A) IN GENERAL.—The drug or substance—

"(i) has—

"(I) a chemical structure that is substantially similar to the chemical structure of a controlled substance in schedule I, II, III, IV, or V; and

"(II) an actual or predicted 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, II, III, IV, or V; and

"(ii) is not—

"(I) listed or otherwise included in any other schedule in this section or by regulation of the Attorney General; and

"(II) with respect to a particular person, subject to an exemption that 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.

"(B) PREDICTED STIMULANT, DEPRESSANT, OR HALLUCINOGENIC EFFECT.—For purpose of this paragraph, a predicted stimulant, depressant, or hallucinogenic effect on the central nervous system may be based on—

"(i) the chemical structure, structure activity relationships, binding receptor assays, or other relevant scientific information about the substance;

"(ii)(I) the current or relative potential for abuse of the substance; and

"(II) the clandestine importation, manufacture, or distribution, or diversion from legitimate channels, of the substance; or

"(iii) the capacity of the substance to cause a state of dependence, including physical or psychological dependence that is similar to or greater than that of a controlled substance in schedule I, II, III, IV, or V."; and

(3) in subsection (c)—

(A) in the matter preceding schedule I, by striking "IV, and V" and inserting "IV, V, and A"; and

(B) by adding at the end the following:

"SCHEDULE A

"(a) Unless specifically excepted or unless listed in another schedule, any of the following substances, as scheduled in accordance with section 201(k)(5):

"(1) 4-fluoroisobutyryl fentanyl.
"(2) Valeryl fentanyl.
"(3) 4-methoxybutyryl fentanyl.
"(4) 4-methylphenethyl acetyl fentanyl.
"(5) 3-furanyl fentanyl.
"(6) Ortho-fluorofentanyl.
"(7) Tetrahydrofuranyl fentanyl.
"(8) Ocfentanil.
"(9) 4-fluorobutyryl fentanyl.
"(10) Methoxyacetyl fentanyl.
"(11) Meta-fluorofentanyl.
"(12) Isobutyryl fentanyl.
"(13) Acryl fentanyl.".

SEC. 3. TEMPORARY AND PERMANENT SCHEDULING OF SCHEDULE A SUBSTANCES.

Section 201 of the Controlled Substances Act (21 U.S.C. 811) is amended by adding at the end the following:

"(k) TEMPORARY AND PERMANENT SCHEDULING OF SCHEDULE A SUBSTANCES.—

"(1) The Attorney General may issue a temporary order adding a drug or substance to schedule A if the Attorney General finds that—

"(A) the drug or other substance satisfies the criteria for being considered a schedule A substance; and

"(B) adding such drug or substance to schedule A will assist in preventing abuse or misuse of the drug or other substance.

"(2) A temporary scheduling 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 temporary scheduling order shall expire not later than 5 years after the date it becomes effective, except that the Attorney General may, during the pendency of proceedings under paragraph (5), extend the temporary scheduling order for up to 180 days.

"(3) A temporary scheduling order issued under paragraph (1) shall be vacated upon the issuance of a permanent order issued under paragraph (5) with regard to the same substance, or upon the subsequent issuance of any scheduling order under this section.

"(4) A temporary scheduling order issued under paragraph (1) shall not be subject to judicial review.

"(5) The Attorney General may, by rule, issue a permanent order adding a drug or other substance to schedule A if such drug or substance satisfies the criteria for being considered a schedule A substance. Such rulemaking may be commenced simultaneously with the issuance of the temporary scheduling order issued under paragraph (1) with regard to the same substance.

"(6) Before initiating proceedings under paragraph (1) or (5), the Attorney General shall transmit notice of an order proposed to be issued to the Secretary of Health and Human Services. In issuing an order under paragraph (1) or (5), the Attorney General shall take into consideration any comments submitted by the Secretary of Health and Human Services in response to a notice transmitted pursuant to this paragraph.

"(7) On the date of the publication of a notice in the Federal Register pursuant to paragraph (2), the Attorney General shall transmit the same notice to Congress. The temporary scheduling order shall take effect according to paragraph (2), except that the temporary scheduling order may be disapproved by Act of Congress within 180 days from the date of publication of the notice in the Federal Register.".

SEC. 4. PENALTIES.

(a) CONTROLLED SUBSTANCES ACT.—The Controlled Substances Act (21 U.S.C. 801 et seq.) is amended—

(1) in section 401(b)(1) (21 U.S.C. 841(b)(1)), by adding at the end the following:

"(F)(i) In the case of any controlled substance in schedule A, 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 not less than 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 not less than 4 years in addition to such term of imprisonment.";

(2) in section 403(a) (21 U.S.C. 843(a))—

(A) in paragraph (8), by striking "or" at the end;

(B) in paragraph (9), by striking the period at the end and inserting "; or"; and

(C) by inserting after paragraph (9) the following:

"(10) to export a substance in violation of the controlled substance laws of the country to which the substance is exported."; and

(3) in section 404 (21 U.S.C. 844), by inserting after subsection (a) the following:

"(b) A person shall not be subject to a criminal or civil penalty under this title or under any other Federal law solely for possession of a schedule A controlled substance.".

(b) CONTROLLED SUBSTANCES IMPORT AND EXPORT ACT.—Section 1010(b) of the Controlled Substances Import and Export Act (21 U.S.C. 960(b)) is amended by adding at the end the following:

"(8) In the case of a violation under subsection (a) involving a controlled substance in schedule A, the person committing such violation 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 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 not more than 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, United States Code, 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 not less than 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 not less than 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.".

SEC. 5. FALSE LABELING OF SCHEDULE A CONTROLLED SUBSTANCES.

(a) IN GENERAL.—Section 305 of the Controlled Substances Act (21 U.S.C. 825) is amended by adding at the end the following:

"(f) FALSE LABELING OF SCHEDULE A CONTROLLED SUBSTANCES.—

"(1) It shall be unlawful to import, export, manufacture, distribute, dispense, or possess with intent to manufacture, distribute, or dispense, a schedule A substance or product containing a schedule A substance, unless the substance or product bears a label clearly identifying a schedule A substance or product containing a schedule A substance 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.".

(b) PENALTIES.—Section 402 of the Controlled Substances Act (21 U.S.C. 842) is amended—

(1) in subsection (a)(16), by inserting "or subsection (f)" after "subsection (e)"; and

(2) in subsection (c)(1)(D), by inserting "or a schedule A substance" after "anabolic steroid".

SEC. 6. REGISTRATION REQUIREMENTS FOR HANDLERS OF SCHEDULE A SUBSTANCES.

(a) CONTROLLED SUBSTANCES ACT.—Section 303 of the Controlled Substances Act (21 U.S.C. 823) is amended by adding at the end the following:

"(k)(1) The Attorney General shall register an applicant to manufacture schedule A substances if—

"(A) the applicant demonstrates that the schedule A substances will be used for research, analytical, or industrial purposes approved by the Attorney General; and

"(B) the Attorney General determines that such registration is consistent with the public interest and with the United States obligations under international treaties, conventions, or protocols in effect on the date of enactment of this subsection.

"(2) In determining the public interest under paragraph (1)(B), the Attorney General shall consider—

"(A) maintenance of effective controls against diversion of particular controlled substances and any controlled substance in schedule A compounded therefrom into other than legitimate medical, scientific, research, or industrial channels, by limiting the importation and bulk manufacture of such controlled substances to a number of establishments which can produce an adequate and uninterrupted supply of these substances under adequately competitive conditions for legitimate medical, scientific, research, and industrial purposes;

"(B) compliance with applicable State and local law;

"(C) promotion of technical advances in the art of manufacturing substances described in subparagraph (A) and the development of new substances;

"(D) prior conviction record of applicant under Federal and State laws relating to the manufacture, distribution, or dispensing of substances described in paragraph (A);

"(E) past experience in the manufacture of controlled substances, and the existence in the establishment of effective control against diversion; and

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

"(3) If an applicant is registered to manufacture controlled substances in schedule I or II under subsection (a), the applicant shall not be required to apply for a separate registration under this subsection.

"(l)(1) The Attorney General shall register an applicant to distribute schedule A substances—

"(A) if the applicant demonstrates that the schedule A substances will be used for research, analytical, or industrial purposes approved by the Attorney General; and

"(B) unless the Attorney General determines that the issuance of such registration is inconsistent with the public interest.

"(2) In determining the public interest under paragraph (1)(B), the Attorney General shall consider—

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

"(B) compliance with applicable State and local law;

"(C) prior conviction record of applicant under Federal or State laws relating to the manufacture, distribution, or dispensing of substances described in subparagraph (A);

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

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

"(3) If an applicant is registered to distribute a controlled substance in schedule I or II under subsection (b), the applicant shall not be required to apply for a separate registration under this subsection.

"(m)(1) Not later than 90 days after the date on which a substance is placed in schedule A, any practitioner who was engaged in research on the substance before the placement of the substance in schedule A and any manufacturer or distributor who was handling the substance before the placement of the substance in schedule A shall register with the Attorney General.

"(2)(A) Not later than 60 days after the date on which the Attorney General receives an application for registration to conduct research on a schedule A substance, the Attorney General shall—

"(i) grant, or initiate proceedings under section 304(c) to deny, the application; or

"(ii) request supplemental information from the applicant.

"(B) Not later than 30 days after the date on which the Attorney General receives supplemental information requested under subparagraph (A)(ii) in connection with

an application described in subparagraph (A), the Attorney General shall grant or deny the application.

"(n)(1) The Attorney General shall register a scientific investigator or a qualified research institution to conduct research with controlled substances in schedule A in accordance with this subsection. In evaluating applications for such registration, the Attorney General shall apply the criteria set forth in subsection (f) of this section that apply to practitioners seeking a registration to conduct research with a schedule I controlled substance, except that the applicant shall not be required to submit a research protocol.

"(2) If the applicant is not currently registered under subsection (f) to conduct research with a schedule I controlled substance, the Attorney General shall refer the application to the Secretary, who shall determine whether the applicant will be engaged in bona fide research and is qualified to conduct such research.

"(3) If the applicant is currently registered under subsection (f) to conduct research with a schedule I controlled substance, the applicant will be considered qualified to conduct research with controlled substances in schedule A and the Attorney General shall modify the applicant's registration to include schedule A controlled substances in accordance with this paragraph. The applicant shall notify the Attorney General of his intent to conduct research with a controlled substance in schedule A. Upon receiving such notification, the Attorney General shall modify the practitioner's existing registration to authorize research with schedule A controlled substances, unless the Attorney General determines that the registration modification would be inconsistent with the public interest based on the criteria of subsection (f).

"(4) Registrations issued under this subsection to a qualified research institution will apply to all agents and employees of that institution acting within the scope of their professional practice.

"(5) At least thirty days prior to conducting any research with a controlled substance in schedule A, the registrant shall provide the Attorney General with written notification of the following:

"(A) The name of and drug code for each substance.

"(B) The name of each individual with access to each substance.

"(C) The amount of each substance.

"(D) Other similar information the Attorney General may require.

"(6) The quantity of a schedule A controlled substance possessed by a person registered under this subsection shall be appropriate for the research being conducted, subject to the additional limitations set forth in this paragraph. To reduce the risk of diversion, the Attorney General may establish limitations on the quantity of schedule A controlled substances that may be manufactured or possessed for purposes of research under this subsection and shall publish such limitations on the website of the Drug Enforcement Administration. A person registered under this subsection may, based on legitimate research needs, apply to the Attorney General to manufacture or possess an amount greater than that so specified by the Attorney General. The Attorney General shall specify the manner in which such applications shall be submitted. The Attorney General shall act on an application filed under this subparagraph within 30 days of receipt of such application. If the Attorney General fails to act within 30 days, the registrant shall be allowed to manufacture and possess up to the amount requested. The Attorney General shall have the authority to reverse the increase for cause.

"(7) The Attorney General shall by regulation specify the manner in which applications for registration under this subsection shall be submitted.

"(8) Registrants authorized under this subsection may manufacture and possess schedule A controlled substances up to the approved amounts only for use in their own research setting or institution. Manufacturing for use in any other setting or institution shall require a manufacturer's registration under section 303(a).".

(b) CONTROLLED SUBSTANCES IMPORT AND EXPORT ACT.—Section 1008 of the Controlled Substances Import and Export Act (21 U.S.C. 958) is amended by adding at the end the following:

"(j)(1) The Attorney General shall register an applicant to import or export a schedule A substance if—

"(A) the applicant demonstrates that the schedule A substances will be used for research, analytical, or industrial purposes approved by the Attorney General; and

"(B) the Attorney General determines that such registration is consistent with the public interest and with the United States obligations under international treaties, conventions, or protocols in effect on the date of enactment of this subsection.

"(2) In determining the public interest under paragraph (1)(B), the Attorney General shall consider the factors described in subparagraphs (A) through (F) of section 303(k)(2).

"(3) If an applicant is registered to import or export a controlled substance in schedule I or II under subsection (a), the applicant shall not be required to apply for a separate registration under this subsection.".

SEC. 7. ADDITIONAL CONFORMING AMENDMENTS.

(a) CONTROLLED SUBSTANCES ACT.—The Controlled Substances Act (21 U.S.C. 801 et seq.) is amended—

(1) in section 303(c) (21 U.S.C. 823(c))—

(A) by striking "subsections (a) and (b)" and inserting "subsection (a), (b), (k), or (l)"; and

(B) by striking "schedule I or II" and inserting "schedule I, II, or A";

(2) in section 306 (21 U.S.C. 826)—

(A) in subsection (a), in the first sentence, by striking "schedules I and II" and inserting "schedules I, II, and A";

(B) in subsection (b), in the second sentence, by striking "schedule I or II" and inserting "schedule I, II, or A";

(C) in subsection (c), in the first sentence, by striking "schedules I and II" and inserting "schedules I, II, and A";

(D) in subsection (d), in the first sentence, by striking "schedule I or II" and inserting "schedule I, II, or A";

(E) in subsection (e), in the first sentence, by striking "schedule I or II" and inserting "schedule I, II, or A"; and

(F) in subsection (f), in the first sentence, by striking "schedules I and II" and inserting "schedules I, II, and A";

(3) in section 308(a) (21 U.S.C. 828(a)), by striking "schedule I or II" and inserting "schedule I, II, or A";

(4) in section 402(b) (21 U.S.C. 842(b)), in the matter preceding paragraph (1), by striking "schedule I or II" and inserting "schedule I, II, or A";

(5) in section 403(a)(1) (21 U.S.C. 843(a)(1)), by striking "schedule I or II" and inserting "schedule I, II, or A"; and

(6) in section 511(f) (21 U.S.C. 881(f)), by striking "schedule I or II" each place it appears and inserting "schedule I, II, or A".

(b) CONTROLLED SUBSTANCES IMPORT EXPORT ACT.—The Controlled Substances Import and Export Act (21 U.S.C. 951 et seq.) is amended—

(1) in section 1002(a) (21 U.S.C. 952(a))—

(A) in the matter preceding paragraph (1), by striking "schedule I or II" and inserting "schedule I, II, or A"; and

(B) in paragraph (2), by striking "schedule I or II" and inserting "schedule I, II, or A";

(2) in section 1003 (21 U.S.C. 953)—

(A) in subsection (c), in the matter preceding paragraph (1), by striking "schedule I or II" and inserting "schedule I, II, or A"; and

(B) in subsection (d), by striking "schedule I or II" and inserting "schedule I, II, or A";

(3) in section 1004(1) (21 U.S.C. 954(1)), by striking "schedule I" and inserting "schedule I or A";

(4) in section 1005 (21 U.S.C. 955), by striking "schedule I or II" and inserting "schedule I, II, or A"; and

(5) in section 1009(a) (21 U.S.C. 959(a)), by striking "schedule I or II" and inserting "schedule I, II, or A".

SEC. 8. CONTROLLED SUBSTANCE ANALOGUES.

Section 102 of the Controlled Substances Act (21 U.S.C. 802) is amended—

(1) in paragraph (6), by striking "or V" and inserting "V, or A";

(2) in paragraph (14)—

(A) by striking "schedule I(c) and" and inserting "schedule I(c), schedule A, and"; and

(B) by striking "schedule I(c)," and inserting "schedule I(c) and schedule A,"; and

(3) in paragraph (32)(A), by striking "(32)(A)" and all that follows through clause (iii) and inserting the following:

"(32)(A) Except as provided in subparagraph (C), the term 'controlled substance analogue' means a substance whose chemical structure is substantially similar to the chemical structure of a controlled substance in schedule I or II—

"(i) 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

"(ii) with respect to a particular person, which such person represents or intends to have a stimulant, depressant, or hallucinogenic effect on the central

nervous system 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.".

SEC. 9. AMENDMENT TO THE SENTENCING GUIDELINES.

Section 2D1.1 of the Federal Sentencing Guidelines is amended, in Application Note 6 (Analogues and Controlled Substances Not Referenced in this Guideline) of the Commentary, by striking "In determining the most closely related controlled substance, the court shall, to the extent practicable, consider the following:" and inserting the following: "In determining the most closely related controlled substance and the applicable guideline or drug equivalence, the court shall—

"(A) if Attorney General has provided guidance on the appropriate sentencing equivalency or ratio to a controlled substance that is referenced in the guidelines through publication in the Federal Register (whether such guidance is included in or separate from any notice of proposed temporary or permanent scheduling of such substance under section 201 of the Controlled Substances Act (21 U.S.C. 811)), apply any such sentencing equivalency or ratio; and

"(B) in the absence of guidance with respect to a substance or group of substances as described in paragraph (A), use equivalencies for the following structural classes of substances as if they were included on the Drug Equivalency Tables:

"Drug Class	Marihuana Equivalency of 1 gm of subject substance
Synthetic Opioids	1 gm = 10 kg
Synthetic Cannabinoids	1 gm = 167 gm
Synthetic Cathinones	1 gm = 380 gm
Tryptamine	1 gm = 80 gm
Phenethylamines	1 gm = 2.5 kg
Piperazines	1 gm = 2 kg
Benzofurans	1 gm = 500 gm
Arylcyclohexylamines (PCP-like substances)	1 gm = 1 kg
Methylphenidate analogs	1 gm = 100 gm
Benzodiazepines	1 'unit' (as defined in Note (F) to the Drug Quantity Table in 2D1.1) = 0.0625 gm

In the case of a substance for which paragraphs (A) and (B) above are not applicable, the court shall determine an equivalency or ratio by considering the following factors, to the extent practicable:".

SEC. 10. RULES OF CONSTRUCTION.

Nothing in this Act, or the amendments made by this Act, may be construed to limit—

(1) the prosecution of offenses involving controlled substance analogues under the Controlled Substances Act (21 U.S.C. 801 et seq.); or

(2) the authority of the Attorney General to temporarily or permanently schedule, reschedule, or decontrol controlled substances under provisions of section 201 of the Controlled Substances Act (21 U.S.C. 811) that are in effect on the day before the date of enactment of this Act.

SEC. 11. STUDY BY COMPTROLLER GENERAL.

Not later than 2 years after the date of enactment of this Act, the Comptroller General of the United States shall complete a study and submit a report to the Committees on the Judiciary of the House of Representatives and of the Senate regarding the costs associated with the amendments made by section 4, including—

(1) the annual amounts expended by Federal agencies in carrying out the amendments;

(2) The costs associated with arrests, trials, convictions, imprisonment, or imposition of other sanctions in accordance with the amendments; and

(3) the impact (including the fiscal impact) of the amendments on existing correctional facilities and the likelihood that those amendments will create a need for additional capacity for housing prisoners.

Purpose and Summary

H.R. 2851 would modernize the Controlled Substances Act (CSA) to provide prompt action to stop the unlawful importation and distribution of synthetic drugs. It establishes a mechanism by which

synthetic drugs can be temporarily and permanently controlled to curtail illicit manufacturing, importation and distribution.

Background and Need for the Legislation

The United States is in the midst of a synthetic drug epidemic. Over 52,000 Americans, or about 144 people per day, died from drug overdoses in 2015. Nearly one-fifth of these deaths resulted from an overdose of synthetic opioids like fentanyl. These synthetic opioids can be as much as 100 times more powerful than painkillers like morphine. Moreover, synthetic analogues, with street names like K2, Spice, Bath Salts, or Molly, are designed to mimic other street drugs like marijuana, LSD, and Ecstasy and can be more potent than the real thing and just as deadly. These drugs have no known legitimate industrial or medical use and their misuse and abuse represents an emerging and ongoing public health and safety crisis in the United States.

Synthetic drugs are analogues of already-controlled substances. Savvy and highly-knowledgeable criminals, and the chemists they employ, are able to slightly modify the chemical structure of a controlled substance. Their goal is that the new (and legal) synthetic drug mimics the effects of a controlled substance. Because the drug is only slightly modified, it still attaches to receptors in the human brain, causing similar but sometimes more intense effects.

Federal and state drug statutes are designed to list each controlled substance by its precise chemical name and structure. It is in this way that all authorized manufacturers, importers, and distributors have knowledge of the requirements for handling that controlled substance under the law. However, it is under this law that illicit manufacturers, importers, and distributors of synthetic drugs are able to slightly modify the chemical structure of substances to avoid responsibility and prosecution.

Illegal drug traffickers and importers are able to circumvent the existing scheduling regime by altering a single atom or molecule of a currently controlled substance in a laboratory, thereby creating a substance that is lawful, but often highly dangerous, addictive, and even deadly. These synthetic analogues are being trafficked into the United States, often from China and Mexico, and pose a grave threat to the health and safety of the American people.

The Controlled Substances Act, enacted over 40 years ago, was not designed to handle the magnitude and speed with which synthetic drugs have emerged in our communities. The Stop the Importation and Trafficking of Synthetic Analogues Act modernizes the CSA to provide swifter action to stop the unlawful importation and distribution of synthetic drugs and gives law enforcement effective tools to help keep our communities safe.

Hearings

The Judiciary Committee's Subcommittee on Crime, Terrorism, Homeland Security and Investigations held one day of hearings on H.R. 2851, the Stop the Trafficking and Importation of Synthetic Analogues (SITSA) Act, on June 27, 2017. Testimony was received from John Katko, Member of Congress; Demetra Ashley, Deputy Assistant Administrator, Drug Enforcement Administration (DEA), Diversion Control; Robert E. Perez, Acting Executive Assistant

Commissioner, U.S. Customs and Border Protection, Operations Support; Marcia Lee Taylor, President and CEO, Partnership for Drug-Free Kids; Reta Newman, Special Advisor to Drug Free America Foundation and Chief Chemist and Laboratory Director of the Pinellas County (Florida) Forensic Laboratory; and Angela Pacheco, former District Attorney, State of New Mexico, First Judicial District.

Committee Consideration

On July 12, 2017, the Committee met in open session and ordered the bill, H.R. 2851, favorably reported, with an amendment, by voice vote, a quorum being present.

Committee Votes

In compliance with clause 3(b) of rule XIII of the Rules of the House of Representatives, the Committee advises that there were no recorded votes during the Committee's consideration of H.R. 2851.

Committee Oversight Findings

In compliance with clause 3(c)(1) of rule XIII of the Rules of the House of Representatives, the Committee advises that the findings and recommendations of the Committee, based on oversight activities under clause 2(b)(1) of rule X of the Rules of the House of Representatives, are incorporated in the descriptive portions of this report.

New Budget Authority and Tax Expenditures

Clause 3(c)(2) of rule XIII of the Rules of the House of Representatives is inapplicable because this legislation does not provide new budgetary authority or increased tax expenditures.

Congressional Budget Office Cost Estimate

In compliance with clause 3(c)(3) of rule XIII of the Rules of the House of Representatives, the Committee sets forth, with respect to H.R. 2851, the following estimate and comparison prepared by the Director of the Congressional Budget Office under section 402 of the Congressional Budget Act of 1974:

CONGRESSIONAL BUDGET OFFICE,
Washington, DC, September 20, 2017.

Hon. BOB GOODLATTE, CHAIRMAN,
Committee on the Judiciary,
House of Representatives, Washington, DC.

DEAR MR. CHAIRMAN: The Congressional Budget Office has prepared the enclosed cost estimate for H.R. 2851, the Stop the Importation and Trafficking of Synthetic Analogues Act of 2017.

If you wish further details on this estimate, we will be pleased to provide them. The CBO staff contact is Mark Grabowicz, who can be reached at 226–2860.

Sincerely,

KEITH HALL.

Enclosure.

cc: Honorable John Conyers Jr.
Ranking Member

H.R. 2851—Stop the Importation and Trafficking of Synthetic Analogues Act of 2017.

As ordered reported by the House Committee on the Judiciary on July 12, 2017.

H.R. 2851 would classify certain drugs, most of which include the pain medication fentanyl, as controlled substances. Individuals who wish to handle those substances, such as researchers or persons conducting chemical analyses, would have to register with the Drug Enforcement Administration (DEA) and pay a fee (usually a few hundred dollars per year, on average). Such fees are treated as reductions in direct spending and DEA is authorized to spend them without further appropriation to cover the cost of overseeing those who register. Based on information from the agency, CBO estimates that DEA would collect (and spend) less than $1 million per year from the additional fees; thus, the net budgetary effect would be negligible.

H.R. 2851 also would establish new federal crimes related to misuse of the controlled substances identified in the bill. As a result, the government might be able to pursue cases that it otherwise would not be able to prosecute. CBO expects that the bill would apply to a relatively small number of offenders, however, so any increase in costs for law enforcement, court proceedings, or prison operations would not be significant. Any such spending would be subject to the availability of appropriated funds.

Because those prosecuted and convicted under H.R. 2851 could be subject to criminal fines, the federal government might collect additional fines under the bill. Criminal fines are recorded as revenues, deposited in the Crime Victims Fund, and later spent without further appropriation action. CBO expects that any additional revenues and associated direct spending would not be significant because the legislation would probably affect only a small number of cases.

Because enacting the bill would affect direct spending and revenues pay-as-you-go procedures apply. However, we estimate that any such effects would be insignificant in any year.

CBO estimates that enacting H.R. 2851 would not increase net direct spending or on-budget deficits in any of the four consecutive 10-year periods beginning in 2028.

By expanding the list of drugs classified as controlled substances, H.R. 2851 would impose an intergovernmental and private-sector mandate as defined in the Unfunded Mandates Reform Act (UMRA). The bill would require individuals and facilities, including public research institutions, that wish to handle those drugs to register (or update their existing registration) with the DEA and comply with any regulatory controls. Based on information from DEA, CBO expects that the registration requirements would apply to hundreds of entities. CBO estimates that the cost to obtain or update a registration would be relatively small. Additionally, public institutions are exempt from the registration fee. Consequently,

CBO estimates that the incremental cost of the mandate on public and private entities would be small and fall below the annual thresholds established in UMRA for intergovernmental and private-sector mandates ($78 million and $156 million in 2017, respectively, adjusted annually for inflation).

The CBO staff contacts for this estimate are Mark Grabowicz (for federal costs), Zach Byrum (for intergovernmental mandates), and Amy Petz (for private-sector mandates). The estimate was approved by H. Samuel Papenfuss, Deputy Assistant Director for Budget Analysis.

Duplication of Federal Programs

No provision of H.R. 2851 establishes or reauthorizes a program of the Federal government known to be duplicative of another Federal program, a program that was included in any report from the Government Accountability Office to Congress pursuant to section 21 of Public Law 111–139, or a program related to a program identified in the most recent Catalog of Federal Domestic Assistance.

Disclosure of Directed Rule Makings

The Committee finds that H.R. 2851 contains no directed rule making within the meaning of 5 U.S.C. § 551.

Performance Goals and Objectives

Pursuant to clause 3(c)(4) of rule XIII of the Rules of the House of Representatives, the Committee states that H.R. 2851 is designed to control the manufacture, importation, and distribution of synthetic drugs and restrict possession to qualified researchers. Specifically, the bill creates a process whereby synthetic drugs which are virtually identical to currently scheduled, dangerous drugs can be expeditiously identified and scheduled appropriately.

Advisory on Earmarks

In accordance with clause 9 of rule XXI of the Rules of the House of Representatives, H.R. 2851 does not contain any congressional earmarks, limited tax benefits, or limited tariff benefits as defined in clause 9(e), 9(f), or 9(g) of rule XXI.

Section-by-Section Analysis

The following discussion describes the bill as reported by the Committee.

Section 1. Short Title. Section 1 sets forth the short title of the bill as the "Stop the Importation and Trafficking of Synthetic Analogues Act (SITSA) of 2017."

Section 2. Establishment of Schedule A. The CSA is currently comprised of five drug schedules (I, II, III, IV, and V). Differentiation among the schedules is based on: 1) currently accepted medical use; 2) the degree of potential for abuse; and 3) the existence or lack of safety for use of the drug under medical supervision. Schedule I drugs have no known medical use and cannot be prescribed. Drugs in Schedules II through V have well-researched medical uses but have varying potentials for addiction and abuse ranging from severe (oxycodone and fentanyl) to low (low-dosage codeine prep-

arations). Due to the very unique production, characteristics, and importation of synthetic drugs, Section 2 establishes a sixth category of controlled substances known as "Schedule A."

This section defines a Schedule A substance. The definition is nearly identical to the current definition for a controlled substance analogue.[1] The proposed Schedule A substance must have a chemical structure that is substantially similar to an existing controlled substance in Schedules I through V, and it must have an actual or predicted physiological effect on the human body equal to or greater than an existing controlled substance in Schedules I through V. By definition, it excludes new substances which are approved by the Food and Drug Administration (FDA) for investigational purposes.

Illicit drug traffickers and importers are able to circumvent the CSA by changing just one atom of an existing controlled substance. Although the change might be considered minor, the physical reaction to each substance can be severe, varying from person to person. Moreover, the research and chemistry communities have had no time or opportunity to analyze the substance's effects. Therefore, this section provides specific and detailed criteria by which the Attorney General must find that the predicted stimulant, depressant, or hallucinogenic effects on the central nervous system are substantially similar to or greater than that of an existing Schedule I through V controlled substance.

This section also adds 13 variations of the drug fentanyl to Schedule A. Fentanyl is a powerful drug designed to treat severe pain (e.g., pain associated with certain late-stage cancers), only while under strict medical supervision. However, drug trafficking organizations and their chemists modify versions of the base fentanyl molecule to create new but similar-acting or sometimes more powerful substances, in order to circumvent the CSA controls. Law enforcement has encountered these modified fentanyls in the United States, Europe, Asia, and Africa. These fentanyls have been confirmed as the cause of death in at least 162 cases in the United States, with several more suspected. Importantly, the bill does not preclude these or future Schedule A drugs from becoming Schedule I through V drugs. It merely places controls upon the drugs, so the illicit trafficking can be halted.

Section 3. Temporary and Permanent Scheduling of Schedule A Substances. Section 3 permits the Attorney General to issue temporary and permanent scheduling orders very similar to those in a 2014 law enacted to curb the trafficking of recently emerged anabolic steroids.[2] This section provides specific criteria upon which the Attorney General must make findings:

1. To issue a temporary order, the Attorney General must find that the substance meets the criteria for inclusion in Schedule A and must find that inclusion in Schedule A will assist in preventing abuse or misuse of the substance.

2. The temporary order cannot take effect until 30 days after the Attorney General publishes notice in the *Federal Register* and states the grounds for inclusion in Schedule A. The temporary order may not last longer than five years, with the ex-

[1] 21 U.S.C. § 802(32)(A).

[2] Designer Anabolic Steroid Control Act of 2014, Pub. L. No. 113–260 (enacted December 18, 2014).

ception that the Attorney General may extend the temporary order for up to 180 days if the substance is in the process of being declared a permanent Schedule A substance. One of the purposes being that the research community must have enough time to analyze and investigate these substances.

When the Attorney General publishes notice in the *Federal Register* to include a substance in Schedule A, notice must also be transmitted to Congress. Congress has the power to disapprove and reverse the temporary scheduling order within 180 days from the date of the *Federal Register* notice.

Section 4. Penalties. Section 4 establishes penalties for manufacturing, distributing, or dispensing Schedule A controlled substances, or possessing with the intent to manufacture, distribute, or dispense Schedule A controlled substances. Although the majority of potential Schedule A substances are most closely related to those in Schedules I and II, the penalties established are the equivalent of those associated with Schedule III controlled substances, such as anabolic steroids. The crime of simple possession is expressly excluded from the possible penalties. Unlike the penalties associated with these offenses for Schedule I or II controlled substances, these penalties do not include mandatory minimum sentences. Penalties for a first offense of trafficking or distribution may include imprisonment of not more than 10 years. Subsequent offenses may include imprisonment of not more than 20 years.

This section also establishes penalties for importing or exporting Schedule A controlled substances, as well as manufacturing or distributing Schedule A controlled substances while intending, knowing, or having reasonable cause to believe these substances will be imported into the United States. These penalties are the equivalent of those associated with these offenses for Schedule I controlled substances, reflecting the importance of punishing and deterring drug trafficking organizations in China and Mexico that import these substances into the United States. Unlike the penalties associated with these offenses for Schedule I controlled substances, these penalties do not include mandatory minimum sentences.

Section 5. False Labeling of Schedule A Controlled Substances. Section 5 adds a new subsection making it unlawful to import, export, manufacture, distribute, dispense, or traffic Schedule A substances unless they are properly labeled. Similar to the Designer Anabolic Steroid Act of 2014, this section requires all entities in the supply chain (e.g. retailers, importers, distributers, etc.) to clearly label the product with the standardized nomenclature used by the International Union of Pure and Applied Chemistry (IUPAC). This section exempts drugs or other substances from the IUPAC nomenclature requirement if the product is labeled in the manner required under the Food, Drug, and Cosmetic Act. IUPAC has long been recognized as the world authority on chemical nomenclature. This section also provides additional civil tools the government can impose to either shut down shops that are in violation of this provision or levy civil fines to go after organizations, retailers, or individuals who traffic synthetic drugs. A substance is exempt from these provisions if it is currently undergoing clinical trials or is subject to FDA approval. Violation of this subsection may include civil penalties of up to $1,000 per violation.

Section 6. Registration Requirements for Handlers of Schedule A Substances. Section 6 requires the Attorney General to register applicants to import, export, manufacture, and/or possess synthetic drugs, provided it is for approved research, analytical, or industrial purposes, and ensures the applicant will prevent diversion of the synthetic drugs.

A practitioner or researcher that is already registered to conduct research on Schedule I substances does not need to obtain a separate registration for Schedule A substances. Similarly, if a person or entity is already registered to manufacture, distribute, or import Schedule I or II substances, then a separate registration is not required. All persons and entities already registered need to comply with security and recordkeeping requirements and notify the Attorney General that they are handling Schedule A substances.

Qualified individuals and research entities not currently registered must apply for a Schedule A registration. This section simplifies the registration requirements and eliminates the need for submission of a research protocol. As most Schedule A substances are quite powerful, limits are placed on the amounts researchers can manufacture and possess, however, a procedure provides for requests for increase based on scientific need.

Any practitioner or researcher who is engaged in researching a substance that is subsequently placed on Schedule A must register within 90 days if not already registered to research Schedule I drugs.

This section also sets strict time limits for action on Schedule A applications. The Attorney General must grant, deny, or request supplemental information within 60 days of receipt of an application. If supplemental information is requested from the applicant, the Attorney General must grant or deny a registration within 30 days after receipt of the requested supplemental information.

Scientific investigators and qualified research institutions shall be registered by the Attorney General to conduct research with Schedule A substances dependent upon certain factors. Applicants currently registered to conduct research on Schedule I substances will be considered qualified to conduct research on Schedule A substances and their registrations will be modified accordingly. Applications from those not currently registered to conduct research on Schedule I substances shall be referred by the Attorney General to the Secretary of Health and Human Services, who shall determine whether the applicant will be engaged in bona fide research and is qualified to conduct such research. Approved registrants must conform to certain notice, quantity, and transfer requirements.

Section 7. Additional Conforming Amendments. Section 7 incorporates Schedule A in the Controlled Substances Import and Export Act (21 U.S.C. 959). It also incorporates requirements and penalties for Schedule A substances into those already existing for substances in Schedules I and II, categories reserved for the most addictive and potentially harmful of all controlled substances. Additions to certain provisions include: 1) controls on importation; exportation, manufacturing, and distribution; 2) setting of production quotas; 3) use of approved order forms (to track legitimate shipments); and 4) forfeiture (of seized substances only).

Section 8. Controlled Substance Analogues. Section 8 is a technical amendment to the definition of a controlled substance ana-

logue[3] that relates to the Analogue Enforcement Act,[4] an existing tool that would be available for prosecutors even after the creation of Schedule A. The current wording of the definition in the statute has created confusion among various district and appellate courts about whether demonstrating any of the three elements of the definition would qualify a substance as a controlled substance analogue, which was not the intent of Congress when the law was passed. This section clarifies that, consistent with the conclusion of a majority of courts that have interpreted it, a substance *must* meet the first element of the definition (the substance's chemical structure must be substantially similar to that of a controlled substance in Schedule I or II) *and then either* of the remaining two elements.

Section 9. Amendment of the Sentencing Guidelines. Section 9 provides guidance in sentencing during the current problematic time for courts, prosecutors, and defendants. Under current law, after a defendant is convicted of violating federal law with regard to a specific controlled substance or an analogue of a controlled substance (21 U.S.C. 813), the court must then look to the sentencing guidelines to calculate the appropriate offense level (and from there, the sentence). This sentence is based on a conversion ratio of the quantity of the drug at issue (typically in grams) to a quantity of marijuana for which a sentencing structure (in months) is applied. The U.S. Sentencing Commission (USSC) has set forth several ratios in the Sentencing Guidelines Drug Equivalency Table.[5] However, due to the adaptability of criminal drug manufacturers, importers, and traffickers, the USSC, the DEA, and the government at large are far behind the curve at establishing criteria and ratios that courts need to apply at sentencing. In a majority of synthetic drug convictions for which a sentencing equivalency does not exist, courts must now undertake a time and resource-intensive process to determine whether the chemical structure and/or physiological effects of the drug at issue (which does not have an equivalency) is substantially similar to that of a drug already referenced in the guidelines.[6] Section 9 is intended to provide specific equivalencies for substances NOT already referenced in the sentencing guidelines. Courts will be able to look at three sources of information before having to undertake this laborious process. These three sources are the U.S. Sentencing Guidelines, guidance on a specific synthetic drug published by the Attorney General in the *Federal Register*, and the Drug Equivalency Table contained in this section. Courts would then be able to follow steps in sentencing defendants for certain drug offenses:

1. If a substance is referenced in the guidelines, as is currently the case, courts must follow the guideline parameters for amounts and offense levels for that substance.

2. If a substance is not referenced in the guidelines, and the Attorney General has provided guidance on the appropriate equivalency or ratio in the *Federal Register,* courts must apply that equivalency or ratio.

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[3] 21 U.S.C. § 802(32).
[4] 21 U.S.C. § 813.
[5] Federal Sentencing Guidelines Manual, § 2D1.1, pg. 166, et seq. (Nov. 2016).
[6] Federal Sentencing Guidelines Manual, § 2D1.1, Application Note 6.

3. If the substance is not referenced in the guidelines, and the Attorney General has not provided guidance on the appropriate equivalency or ratio in the *Federal Register,* courts must use the equivalency provided in the table contained in this section.

4. If the substance is not referenced in the guidelines, and the Attorney General has not provided guidance on the appropriate equivalency or ratio in the *Federal Register,* and courts cannot use the equivalency provided in the table (because the substance is not part of a specified structural class), the court shall determine an equivalency or ratio by applying the factors in application note 6 (as is currently the case for all substances not referenced in the guidelines).

It is highly important to note that although courts are required to consult the guidelines and apply all of its provisions and calculate recommended guideline ranges, pursuant to U.S. Supreme Court decisions, courts are then free to depart from the guidelines.[7] Moreover, if further evidence over time reveals an imbalance in an existing equivalency established by the USSC, the Attorney General's guidance, or the table, the USSC has the option to add that substance to the sentencing guidelines, amend an equivalency, or provide its own quantity thresholds and associated offense levels.

Currently, the government, in the absence of direct guidance, must persuade a judge on the appropriate sentencing ratio for each individual case and each substance. This sometimes leads to inconsistent sentences and ratios for synthetic analogues, even for the same substance. This section will help to bring clarity and uniformity to sentencing.

Section 10. Rules of Construction. Section 10 clarifies that nothing in the bill affects the ability of the Attorney General to schedule, re-schedule, or decontrol substances under the current Controlled Substances Act, or to prosecute offenses under the Analogue Enforcement Act,[8] or any other portion of the Controlled Substances Act. Thus, even after a substance is placed on Schedule A, the government may still subsequently seek to place it on another schedule instead, or to decontrol it, after more information about the substance is acquired. In addition, even after a substance is placed on Schedule A, the government could still attempt to prosecute a trafficker using the Analogue Enforcement Act, if appropriate in a given circumstance.

Section 11. Study by Comptroller General. Section 11 requires the Comptroller General of the United States to conduct a study on the costs associated with Section 4 of this bill.

Changes in Existing Law Made by the Bill, as Reported

In compliance with clause 3(e) of rule XIII of the Rules of the House of Representatives, changes in existing law made by the bill, as reported, are shown as follows (existing law proposed to be omitted is enclosed in black brackets, new matter is printed in italics, and existing law in which no change is proposed is shown in roman):

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[7] *U.S. v. Booker,* 543 U.S. 220 (2005); see also *Blakely v. Washington,* 542 U.S. 296 (2004).
[8] U.S.C. 813.

CONTROLLED SUBSTANCES ACT

TITLE II—CONTROL AND ENFORCEMENT

PART A—SHORT TITLE; FINDINGS AND DECLARATION; DEFINITIONS

* * * * * * *

DEFINITIONS

SEC. 102. 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] *V, or A* 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 I(c), schedule A, and* schedule II(a)(4). As used in ⟦schedule I(c),⟧ *schedule I(c) and schedule A,* 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) The term "marihuana" means all parts of the plant Cannabis sativa L., whether growing or not; the seeds thereof; the resin extracted from any part of such plant; and every compound, manufacture, salt, derivative, mixture, or preparation of such plant, its seeds or resin. Such term does not include the mature stalks of such plant, fiber produced from such stalks, oil or cake made from the seeds of such plant, any other compound, manufac-

ture, 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, Education, and Welfare.

(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) 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—**]** *Except as provided in subparagraph (C), the term "controlled substance analogue" means a substance whose chemical structure is substantially similar to the chemical structure of a controlled substance in schedule I or II—*

[(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.**]**

(i) 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

(ii) with respect to a particular person, which such person represents or intends to have a stimulant, depressant, or hallucinogenic effect on the central nervous system 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 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.

(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 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) Potassium permanaganate.
(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 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) 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 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 303 who do not dispense controlled substances to an unregistered individual or entity;

(ii) nonpharmacy practitioners who are registered under section 303(f) 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(f);

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

(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(f) 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(f) in any State or is using the registration of a hospital or clinic

operated by the Department of Veterans Affairs registered under section 303(f);

(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(f) 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(f);

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

PART B—AUTHORITY TO CONTROL; STANDARDS AND SCHEDULES

SEC. 201. AUTHORITY AND CRITERIA FOR CLASSIFICATION OF SUBSTANCES (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.

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 without regard to the procedures prescribed by subsections (a) and (b) of this section.

(2) (A) Whenever the Secretary of State receives notification from the Secretary-General of the United Nations that information has been transmitted by or to the World Health Organization, pursuant to article 2 of the Convention on Psychotropic Substances, which may justify adding a drug or other substance to one of the schedules of the Convention, transferring a drug or substance from one schedule to another, or deleting it from the schedules, the Secretary of State shall immediately transmit the notice to the Secretary of Health, Education, and Welfare 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) 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 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) If the Attorney General determines, after consultation with the Secretary of Health, Education, and Welfare, that proceedings initiated under recommendations made under paragraph (B) or (C)(i) of paragraph (3) will not be completed within the time period required by paragraph 7 of article 2 of the Convention, the Attorney General, after consultation with the Secretary and after providing interested persons opportunity to submit comments respecting the requirements of the temporary order to be issued under this sentence, shall issue a temporary order controlling the drug or substance under schedule IV or V, whichever is most appropriate to carry out the minimum United States obligations under paragraph 7 of article 2 of the Convention. As a part of such order, the Attorney General shall, after consultation with the Secretary, except such drug or substance from the application of any provision of part C of this title 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 pro-

visions 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.) 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 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 para-

graph (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).

(k) TEMPORARY AND PERMANENT SCHEDULING OF SCHEDULE A SUBSTANCES.—

(1) The Attorney General may issue a temporary order adding a drug or substance to schedule A if the Attorney General finds that—

(A) the drug or other substance satisfies the criteria for being considered a schedule A substance; and

(B) adding such drug or substance to schedule A will assist in preventing abuse or misuse of the drug or other substance.

(2) A temporary scheduling 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 temporary scheduling order shall expire not later than 5 years after the date it becomes effective, except that the Attorney General may, during the pendency of proceedings under paragraph (5), extend the temporary scheduling order for up to 180 days.

(3) A temporary scheduling order issued under paragraph (1) shall be vacated upon the issuance of a permanent order issued under paragraph (5) with regard to the same substance, or upon the subsequent issuance of any scheduling order under this section.

(4) A temporary scheduling order issued under paragraph (1) shall not be subject to judicial review.

(5) The Attorney General may, by rule, issue a permanent order adding a drug or other substance to schedule A if such drug or substance satisfies the criteria for being considered a schedule A substance. Such rulemaking may be commenced simultaneously with the issuance of the temporary scheduling order issued under paragraph (1) with regard to the same substance.

(6) Before initiating proceedings under paragraph (1) or (5), the Attorney General shall transmit notice of an order proposed to be issued to the Secretary of Health and Human Services. In issuing an order under paragraph (1) or (5), the Attorney General shall take into consideration any comments submitted by the Secretary of Health and Human Services in response to a notice transmitted pursuant to this paragraph.

(7) On the date of the publication of a notice in the Federal Register pursuant to paragraph (2), the Attorney General shall transmit the same notice to Congress. The temporary scheduling order shall take effect according to paragraph (2), except that the temporary scheduling order may be disapproved by Act of Congress within 180 days from the date of publication of the notice in the Federal Register.

SCHEDULES OF CONTROLLED SUBSTANCES

SEC. 202. (a) There are established **[**five schedules of controlled substances, to be known as schedules I, II, III, IV, and V**]** *six schedules of controlled substances, to be known as schedules I, II, III, IV, V, and A*. 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.

(6) SCHEDULE A.—

(A) IN GENERAL.—The drug or substance—

(i) has—

(I) a chemical structure that is substantially similar to the chemical structure of a controlled substance in schedule I, II, III, IV, or V; and

(II) an actual or predicted 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, II, III, IV, or V; and

(ii) is not—

(I) listed or otherwise included in any other schedule in this section or by regulation of the Attorney General; and

(II) with respect to a particular person, subject to an exemption that 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.

(B) PREDICTED STIMULANT, DEPRESSANT, OR HALLUCINOGENIC EFFECT.—For purpose of this paragraph, a predicted stimulant, depressant, or hallucinogenic effect on the central nervous system may be based on—

(i) the chemical structure, structure activity relationships, binding receptor assays, or other relevant scientific information about the substance;

(ii)(I) the current or relative potential for abuse of the substance; and

(II) the clandestine importation, manufacture, or distribution, or diversion from legitimate channels, of the substance; or

(iii) the capacity of the substance to cause a state of dependence, including physical or psychological dependence that is similar to or greater than that of a controlled substance in schedule I, II, III, IV, or V.

(c) Schedules I, II, III, [IV, and V] *IV, V, and A* 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 A

(a) Unless specifically excepted or unless listed in another schedule, any of the following substances, as scheduled in accordance with section 201(k)(5):

(1) 4-fluoroisobutyryl fentanyl.
(2) Valeryl fentanyl.
(3) 4-methoxybutyryl fentanyl.
(4) 4-methylphenethyl acetyl fentanyl.
(5) 3-furanyl fentanyl.
(6) Ortho-fluorofentanyl.
(7) Tetrahydrofuranyl fentanyl.
(8) Ocfentanil.
(9) 4-fluorobutyryl fentanyl.
(10) Methoxyacetyl fentanyl.
(11) Meta-fluorofentanyl.
(12) Isobutyryl fentanyl.
(13) Acryl fentanyl.

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

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REGISTRATION REQUIREMENTS

SEC. 303. (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 substances under adequately competitive conditions for legitimate medical, scientific, research, and industrial purposes;

(2) compliance with applicable State and local law;

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

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

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

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

(b) 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) Registration granted under [subsections (a) and (b)] *subsection (a), (b), (k), or (l)* of this section shall not entitle a registrant to (1) manufacture or distribute controlled substances in [schedule I or II] *schedule I, II, or A* 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.

(d) The Attorney General shall register an applicant to manufacture controlled substances in schedule III, IV, or V, unless he determines that the issuance of such registration is inconsistent with

the public interest. In determining the public interest, the following factors shall be considered:

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

(2) compliance with applicable State and local law;

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

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

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

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

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

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

(2) compliance with applicable State and local law;

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

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

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

(f) 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:

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

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

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

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

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

Separate registration under this part 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. Registration applications by practitioners wishing to conduct research with controlled substances in schedule I shall be referred to the Seretary, 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). 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.

(g)(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;

(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 detoxi-

fication 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 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.

(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 (f).

(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 (f).

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

(II) 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.

(iii) The term "qualifying practitioner" means—

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

(II) during the period beginning on the date of enactment of the Comprehensive Addiction and Recovery Act of 2016 and ending on October 1, 2021, a qualifying other practitioner, as defined in clause (iv).

(iv) The term "qualifying other practitioner" means a nurse practitioner or physician assistant who satisfies each of the following:

(I) The nurse practitioner 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 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 Physician 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 or physician assistant to treat and manage opiate-dependent patients.

(III) The nurse practitioner or physician assistant is supervised by, or works in collaboration with, a qualifying physician, if the nurse practitioner 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, 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—

(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.

(h) 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.

(i)(1) For purposes of registration to manufacture a controlled substance under subsection (d) 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.

(j) 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.

(k)(1) The Attorney General shall register an applicant to manufacture schedule A substances if—

(A) the applicant demonstrates that the schedule A substances will be used for research, analytical, or industrial purposes approved by the Attorney General; and

(B) the Attorney General determines that such registration is consistent with the public interest and with the United States obligations under international treaties, conventions, or protocols in effect on the date of enactment of this subsection.

(2) In determining the public interest under paragraph (1)(B), the Attorney General shall consider—

(A) maintenance of effective controls against diversion of particular controlled substances and any controlled substance in schedule A compounded therefrom into other than legitimate medical, scientific, research, or industrial channels, by limiting the importation and bulk manufacture of such controlled substances to a number of establishments which can produce an adequate and uninterrupted supply of these substances under adequately competitive conditions for legitimate medical, scientific, research, and industrial purposes;

(B) compliance with applicable State and local law;

(C) promotion of technical advances in the art of manufacturing substances described in subparagraph (A) and the development of new substances;

(D) prior conviction record of applicant under Federal and State laws relating to the manufacture, distribution, or dispensing of substances described in paragraph (A);

(E) past experience in the manufacture of controlled substances, and the existence in the establishment of effective control against diversion; and

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

(3) If an applicant is registered to manufacture controlled substances in schedule I or II under subsection (a), the applicant shall not be required to apply for a separate registration under this subsection.

(l)(1) The Attorney General shall register an applicant to distribute schedule A substances—

(A) if the applicant demonstrates that the schedule A substances will be used for research, analytical, or industrial purposes approved by the Attorney General; and

(B) unless the Attorney General determines that the issuance of such registration is inconsistent with the public interest.

(2) In determining the public interest under paragraph (1)(B), the Attorney General shall consider—

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

(B) compliance with applicable State and local law;

(C) prior conviction record of applicant under Federal or State laws relating to the manufacture, distribution, or dispensing of substances described in subparagraph (A);

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

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

(3) If an applicant is registered to distribute a controlled substance in schedule I or II under subsection (b), the applicant shall not be required to apply for a separate registration under this subsection.

(m)(1) Not later than 90 days after the date on which a substance is placed in schedule A, any practitioner who was engaged in research on the substance before the placement of the substance in schedule A and any manufacturer or distributor who was handling the substance before the placement of the substance in schedule A shall register with the Attorney General.

(2)(A) Not later than 60 days after the date on which the Attorney General receives an application for registration to conduct research on a schedule A substance, the Attorney General shall—

(i) grant, or initiate proceedings under section 304(c) to deny, the application; or

(ii) request supplemental information from the applicant.

(B) Not later than 30 days after the date on which the Attorney General receives supplemental information requested under subparagraph (A)(ii) in connection with an application described in subparagraph (A), the Attorney General shall grant or deny the application.

(n)(1) The Attorney General shall register a scientific investigator or a qualified research institution to conduct research with controlled substances in schedule A in accordance with this subsection. In evaluating applications for such registration, the Attorney General shall apply the criteria set forth in subsection (f) of this section that apply to practitioners seeking a registration to conduct research with a schedule I controlled substance, except that the applicant shall not be required to submit a research protocol.

(2) If the applicant is not currently registered under subsection (f) to conduct research with a schedule I controlled substance, the At-

torney General shall refer the application to the Secretary, who shall determine whether the applicant will be engaged in bona fide research and is qualified to conduct such research.

(3) If the applicant is currently registered under subsection (f) to conduct research with a schedule I controlled substance, the applicant will be considered qualified to conduct research with controlled substances in schedule A and the Attorney General shall modify the applicant's registration to include schedule A controlled substances in accordance with this paragraph. The applicant shall notify the Attorney General of his intent to conduct research with a controlled substance in schedule A. Upon receiving such notification, the Attorney General shall modify the practitioner's existing registration to authorize research with schedule A controlled substances, unless the Attorney General determines that the registration modification would be inconsistent with the public interest based on the criteria of subsection (f).

(4) Registrations issued under this subsection to a qualified research institution will apply to all agents and employees of that institution acting within the scope of their professional practice.

(5) At least thirty days prior to conducting any research with a controlled substance in schedule A, the registrant shall provide the Attorney General with written notification of the following:

(A) The name of and drug code for each substance.

(B) The name of each individual with access to each substance.

(C) The amount of each substance.

(D) Other similar information the Attorney General may require.

(6) The quantity of a schedule A controlled substance possessed by a person registered under this subsection shall be appropriate for the research being conducted, subject to the additional limitations set forth in this paragraph. To reduce the risk of diversion, the Attorney General may establish limitations on the quantity of schedule A controlled substances that may be manufactured or possessed for purposes of research under this subsection and shall publish such limitations on the website of the Drug Enforcement Administration. A person registered under this subsection may, based on legitimate research needs, apply to the Attorney General to manufacture or possess an amount greater than that so specified by the Attorney General. The Attorney General shall specify the manner in which such applications shall be submitted. The Attorney General shall act on an application filed under this subparagraph within 30 days of receipt of such application. If the Attorney General fails to act within 30 days, the registrant shall be allowed to manufacture and possess up to the amount requested. The Attorney General shall have the authority to reverse the increase for cause.

(7) The Attorney General shall by regulation specify the manner in which applications for registration under this subsection shall be submitted.

(8) Registrants authorized under this subsection may manufacture and possess schedule A controlled substances up to the approved amounts only for use in their own research setting or institution. Manufacturing for use in any other setting or institution shall require a manufacturer's registration under section 303(a).

* * * * * * *

LABELING AND PACKAGING REQUIREMENTS

SEC. 305. (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.

(f) FALSE LABELING OF SCHEDULE A CONTROLLED SUBSTANCES.—

(1) It shall be unlawful to import, export, manufacture, distribute, dispense, or possess with intent to manufacture, distribute, or dispense, a schedule A substance or product con-

taining a schedule A substance, unless the substance or product bears a label clearly identifying a schedule A substance or product containing a schedule A substance 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. (a) The Attorney General shall determine the total quantity and establish production quotas for each basic class of controlled substance in [schedules I and II] *schedules I, II, and A* 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. Production quotas shall be established in terms of quantities of each basic class of controlled substance and not in terms of individual pharmaceutical dosage forms prepared from or containing such a controlled substance.

(b) The Attorney General shall limit or reduce individual production quotas to the extent necessary to prevent the aggregate of individual quotas from exceeding the amount determined necessary each year by the Attorney General under subsection (a). The quota of each registered manufacturer for each basic class of controlled substance in [schedule I or II] *schedule I, II, or A* 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 October 1 of each year, upon application therefor by a registered manufacturer, the Attorney General shall fix a manufacturing quota for the basic classes of controlled substances in [schedules I and II] *schedules I, II, and A* 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 dis-

posal, 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] *schedule I, II, or A* 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] *schedule I, II, or A* 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] *schedules I, II, and A* 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.

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ORDER FORMS

SEC. 308. (a) It shall be unlawful for any person to distribute a controlled substance in [schedule I or II] *schedule I, II, or A* 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 Attorney General in blank in accordance with subsection (d) and regulations prescribed by him pursuant to this section, and shall, if such order is accepted, preserve such duplicate for a period of two years and make it available for inspection and copying by the officers and employees mentioned in paragraph (1) of this subsection.

(d)(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 furnishsuch 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.

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PART D—OFFENSES AND PENALTIES

PROHIBITED ACTS A—PENALTIES

SEC. 401. (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 felony drug offense has become final, such person shall be sentenced to a term of imprisonment which may not be less than 20 years and not more than life imprisonment and if death or serious bodily injury results from the use of such substance shall be sentenced to life imprisonment, a fine not to exceed the greater of twice that authorized in accordance with the provisions of title 18, United States Code, or $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 two or more prior convictions for a felony drug offense have become final, such person shall be sentenced to a mandatory term of life imprisonment without release and fined in accordance with the preceding sentence. Notwithstanding section 3583 of title 18, 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; or

(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;

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 felony drug offense has become final, such person shall be sentenced to a term of imprisonment which may not be less than 10 years and not more than life imprisonment and if death or serious bodily injury results from the use of such substance shall be sentenced to life imprisonment, a fine not to exceed the greater of twice that authorized in accordance with the provisions of title 18, United States Code, or $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, 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 ap-

proved 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, any sentence imposing a term of imprisonment under this paragraph shall, in the absence of such a prior conviction, impose a term of supervised release of at least 3 years in addition to such term of imprisonment and shall, if there was such a prior conviction, impose a term of supervised release of at least 6 years in addition to such term of imprisonment. Notwithstanding any other provision of law, the court shall not place on probation or suspend the sentence of any person sentenced under the provisions of this subparagraph which provide for a mandatory term of imprisonment if death or serious bodily injury results, nor shall a person so sentenced be eligible for parole during the term of such a sentence.

(D) In the case of less than 50 kilograms of marihuana, except in the case of 50 or more marihuana plants regardless of weight, 10 kilograms of hashish, or one kilogram of hashish oil, 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, 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.

(F)(i) In the case of any controlled substance in schedule A, 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 not less than 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 not less than 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(f) (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(f) 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. (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); or

(16) to violate subsection (e) *or subsection (f)* of section 825 of this title.

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⟧ *schedule I, II, or A*, 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) In the case of a violation of paragraph (5) or (10) of subsection (a), the civil penalty shall not exceed $10,000.

(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 violation 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 *or a schedule A substance* 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) 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.

(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. (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] *schedule I, II, or A*, 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 ma-

chine, 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**[**.**]***; or*

(10) to export a substance in violation of the controlled substance laws of the country to which the substance is exported.

(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) 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(f).

(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 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; 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.

(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. (a) It shall be unlawful for any person knowingly or intentionally to possess a controlled substance unless such substance was obtained directly, or pursuant to a valid prescription or order, from a practitioner, while acting in the course of his professional practice, or except as otherwise authorized by this title or title III.

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.

(b) A person shall not be subject to a criminal or civil penalty under this title or under any other Federal law solely for possession of a schedule A controlled substance.

(c) 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.

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PART E—ADMINISTRATIVE AND ENFORCEMENT PROVISIONS

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FORFEITURES

SEC. 511. (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 authorized 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 civily 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⟧ *schedule I, II, or A* 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⟧ *schedule I,*

II, or A, 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] *schedule I, II, or A* 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) 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.

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CONTROLLED SUBSTANCES IMPORT AND EXPORT ACT

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TITLE III—IMPORTATION AND EXPORTATION; AMENDMENTS AND REPEALS OF REVENUE LAWS

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PART A—IMPORTATION AND EXPORTATION

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IMPORTATION OF CONTROLLED SUBSTANCES

SEC. 1002. (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] *schedule I, II, or A* 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] *schedule I, II, or A* 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. (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⟧ *schedule I, II, or A* 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⟧ *schedule I, II, or A* 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. Notwithstanding sections 1002, 1003, and 1007—

(1) A controlled substance in [schedule I] *schedule I or A* 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. 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] *schedule I, II, or A* 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.

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REGISTRATION REQUIREMENTS

SEC. 1008. (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(d) 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(h).

(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 substances, 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, re-

voked, 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) The Attorney General is authorized to promulgate rules and regulations and to charge reasonable fees relating to the registration 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.

(j)(1) The Attorney General shall register an applicant to import or export a schedule A substance if—

(A) the applicant demonstrates that the schedule A substances will be used for research, analytical, or industrial purposes approved by the Attorney General; and

(B) the Attorney General determines that such registration is consistent with the public interest and with the United States obligations under international treaties, conventions, or protocols in effect on the date of enactment of this subsection.

(2) In determining the public interest under paragraph (1)(B), the Attorney General shall consider the factors described in subparagraphs (A) through (F) of section 303(k)(2).

(3) If an applicant is registered to import or export a controlled substance in schedule I or II under subsection (a), the applicant shall not be required to apply for a separate registration under this subsection.

POSSESSION, MANUFACTURE OR DISTRIBUTION FOR PURPOSES OF UNLAWFUL IMPORTATION

SEC. 1009. (a) It shall be unlawful for any person to manufacture or distribute a controlled substance in **[**schedule I or II**]** *schedule I, II, or A* 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 tomanufacture or distribute a listed chemical—

(1) intending or knowing that the listedchemical will be used to manufacture a controlled substance; and

(2) intending, knowing, or having reasonablecause to believe that the controlled substance will be unlawfully imported intothe UnitedStates.

(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) This section is intended to reach acts of manufacture or distribution committed outside the territorial jurisdiction of the United States. Any person who violates this section shall be tried in the United States district court at the point of entry where such person enters the United States, or in the United States District Court for the District of Columbia.

PROHIBITED ACTS A—PENALTIES

SEC. 1010. (a) Any person who—

(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.

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 felony drug offense has become final, such person shall be sentenced to a term of imprisonment of not less than 20 years and not more than life imprisonment and if death or serious bodily injury results from the use of such substance shall be sentenced to

life imprisonment, a fine not to exceed the greater of twice that authorized in accordance with the provisions of title 18, United States Code, or $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, 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 or substance containing a detectable amount of methamphetamine, its salts, isomers, or salts of its isomers.

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 felony drug offense 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, 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 or $10,000,000 if the defendant is other than an individual, or both. Notwithstanding section 3583 of title 18, 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).

(8) In the case of a violation under subsection (a) involving a controlled substance in schedule A, the person committing such violation 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 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 not more than 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, United States Code, 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 not less than 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 not less than 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.

(c) 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 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.

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.

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Dissenting Views

H.R. 2851, the "Stop the Importation and Trafficking of Synthetic Analogues Act of 2017" or "SITSA" Act, is well-intended, but flawed legislation that is designed to enhance the ability of federal law enforcement, specifically the Department of Justice and the Drug Enforcement Administration (DEA), to prohibit the manufacture, distribution, and trafficking of analogues of synthetic drugs through temporary and permanent scheduling. This legislation will expand penalties for drug offenses, concentrate an overwhelming amount of unchecked power within the Department of Justice, eliminate scientific and medical analysis and interagency collaboration from the process of scheduling synthetic analogues, over-criminalize certain conduct, and punish individuals without proof of in-

tent. Not surprisingly, the bill is strongly opposed by a broad spectrum of stakeholders, representing many different interests.[1]

For these reasons and those explained below, we must respectfully dissent and urge our colleagues to oppose this flawed legislation.

DESCRIPTION AND BACKGROUND

DESCRIPTION

H.R. 2851, the "Stop the Importation and Trafficking of Synthetic Analogues Act of 2017," amends title 21 of the United States Code, the Controlled Substances Act (CSA), to: (1) create a new schedule for synthetic analogues—Schedule A; (2) place 13 fentanyl analogues on Schedule A upon enactment of the bill; and (3) establish an abbreviated procedure to be conducted exclusively by the Attorney General (as delegated to the DEA) for temporary and permanent placement of drugs or substances on Schedule A that have a chemical structure substantially and an actual or predicted psychoactive effect similar to a controlled substance in Schedules I, II, III, IV, or V. Drugs or substances that meet the criteria for Schedule A may be permanently scheduled or temporarily placed on the schedule by the Attorney General for up to five years with the ability to extend temporary placement for 180 days. Other than the Department of Health and Human Services (HHS), interested parties or agencies would not have the opportunity to comment or request a hearing on proposed scheduling orders. The Attorney General would only be required to consider comments on proposed scheduling orders made by HHS. The bill also establishes penalties including mandatory terms of supervised release for the offenses of manufacturing, distributing, exportation, importation, and dispensing Schedule A substances; possession with intent to do such activities involving Schedule A substances; and retail-related offenses involving Schedule A substances. Finally, the bill establishes procedures, requirements, and criteria for registration of practitioners seeking to manufacture, distribute, import, export, or conduct research with Schedule A substances.

BACKGROUND

Because manufacturers of illicit synthetic drugs change the chemical composition slightly by modifying the molecular structures of illegal or controlled substances, many of them are largely

[1] Letter from David R. Sibley, Ph.D, President, American Society for Pharmacology and Experimental Therapeutics, to Rep. Bob Goodlatte, Chairman, H. Comm. on the Judiciary, & Rep. John Conyers, Jr., Ranking Member, H. Comm. on the Judiciary (June 27, 2017) (on file with Democratic staff of the H. Comm. on the Judiciary); Letter from James C. Duff, Secretary, Judicial Conference of the United States, to Ranking Member Shelia Jackson Lee, Subcomm. on Crime, Terrorism, Homeland Security, and Investigations, H. Comm. on the Judiciary (July 7, 2017) (on file with H. Comm. on the Judiciary Democratic Staff); Letter from Vanita Gupta, President & CEO, The Leadership Conference, to Rep. Bob Goodlatte, Chairman, H. Comm. on the Judiciary, & Rep. John Conyers, Jr., Ranking Member, H. Comm. on the Judiciary (July 11, 2017) (on file with Democratic staff of the H. Comm. on the Judiciary); Letter from Jason Pye, Vice President of Legislative Affairs, FreedomWorks, Pat Nolan, Director of the Center for Criminal Justice Reform, American Conservative Union Foundation, David Barnes, Policy director, Generation Opportunity & David Williams, President, Taxpayers Protection Alliance, to Rep. Bob Goodlatte, Chairman, H. Comm. on the Judiciary, & Rep. John Conyers, Jr., Ranking Member, H. Comm. on the Judiciary (July 11, 2017) (on file with Democratic staff of the H. Comm. on the Judiciary); Letter from coalition of sixty-eight civil and human rights, faith, and criminal justice reform organizations, to Rep. Bob Goodlatte, Chairman, H. Comm. on the Judiciary, & Rep. John Conyers, Jr., Ranking Member, H. Comm. on the Judiciary (July 12, 2017) (on file with Democratic staff of the H. Comm. on the Judiciary).

or completely unknown in terms of scientific data and human experience. These small variations allow the manufacturers to circumvent existing regulatory legislation, resulting in profound and often deadly consequences.[2]

Although the landscape for these drugs is changing, the problem is not new. In response to the emergence of synthetic drugs, or "designer drugs" such as MDMA (Ecstasy), synthetic analogues were added to the CSA in 1986.[3] The Controlled Substance Analogue Enforcement Act of 1986 (AEA) amended the CSA to create a legal basis for controlling unscheduled drugs, placing more effective controls on new chemical variants of already controlled substances and serving as a method of criminalizing synthetic drugs without having to ban them individually. The Act provides that any chemical "substantially similar" to a controlled substance listed in Schedule I or II of the CSA is to be legally treated as though it were also listed in Schedule I.[4] To be treated as an analogue under the AEA, a substance must be intended for human consumption and have a substantially similar chemical structure and cause a substantially similar stimulant, depressant, or hallucinogenic effect to that of a controlled substance in Schedule I or II of the CSA.[5]

As previously mentioned, the chemical structure of synthetic drugs can be manipulated such that it is not chemically the same as a controlled substance, but is structurally similar and will produce pharmacological effects similar to a controlled substance. Theses manipulations occur continuously, effectively creating new analogue substances and allowing illicit drug manufacturers to remain one step ahead of researchers and law enforcement. The DEA reports that prosecution of drug cases under the Analogue Act has proven challenging primarily because the AEA does not establish per se regulation (scheduling) upon identification of an analogue. Each criminal prosecution must establish anew that a particular substance is a controlled substance analogue under the CSA; prosecutors must prove the substance was intended for human consumption; and federal courts maintain a high standard when interpreting whether a substance is substantially similar. As explained by Demetra Ashley, Acting Assistant Administrator of the DEA's Diversion Control Division, "the process is workable, but resource-intensive for DEA, federal prosecutors serving in United States Attorney's Offices, the defense bar, and the court system." [6]

Intended to address concerns about the current mechanisms of regulating these synthetic analogues, H.R. 2851 seeks to simplify and condense the process of scheduling, regulating, and prohibiting synthetic analogues, and provide uniformity in the prosecution of cases involving synthetic analogues. It would create a new schedule of the Controlled Substances Act—Schedule A, on which synthetic analogues of drugs and substances on Schedules I, II, III, IV, or V could be placed—and establish abbreviated procedures for placing

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[2] K. Finklea, *Synthetic Drugs: Overview and Issues for Congress*, Congressional Research Serv. Rep. No. R42066 (2016).

[3] *See* Gregory Kau, *Flashback to the Federal Analog Act of 1986: Mixing Rules and Standards in the Cauldron*,156 U. PA. L. Rev. 1077 (2008).

[4] *See* 21 U.S.C. § 813 (2017).

[5] *See* 21 U.S.C. § 802(32)(A) (2017).

[6] *Stop the Importation and Trafficking of Synthetic Analogues Act of 2017: Hearing on H.R. 2851 Before the Subcomm. on Crime, Terrorism, Homeland Security, and Investigations of the H. Comm. on the Judiciary*, 115th Cong. (2017) (prepared statement of Demetra Ashley, Acting Assistant Administrator, Diversion Control Division, DEA).

drugs and substances on Schedule A. The bill would authorize the Attorney General to order permanent placement on Schedule A if a drug or substance is not already scheduled or otherwise regulated; is not exempted for research purposes, with respect to licensed experts; has a chemical structure that is substantially similar to an existing controlled substances in Schedules I through V; and has an actual or predicted physiological effect on the body equal to or greater than an existing controlled substance in Schedules I through V. The legislation would also allow the Attorney General to order temporary placement of a drug or substance on Schedule A to prevent abuse or misuse of a drug or substance. Before initiating temporary or permanent scheduling, the Attorney General must provide notice to the HHS and would only be required to consider comments submitted by HHS in response to such notices when issuing temporary or permanent scheduling orders.

In addition, the bill would establish penalties including mandatory minimum terms of supervised release for the offenses of manufacturing, distributing, exportation, importation, and dispensing Schedule A substances; possession with intent to do such activities involving Schedule A substances; and retail-related offenses involving Schedule A substances. Application Note 6 of Section 2D1.1 of the Federal Sentencing Guidelines would be amended to outline the procedure for sentencing courts to determine the most closely related controlled substance to a synthetic analogue and, thus, the applicable guideline or drug equivalence for offenses involving analogues and controlled substances not referenced in this Guideline. The drug equivalencies will be set by the Attorney General and in cases where the Attorney General offers no guidance on equivalencies for particular substances, this section provides equivalency tables.

Finally, H.R. 2851 would establish procedures, requirements, and criteria to be administered by the Attorney General for registration of practitioners seeking to manufacture, distribute, import, export, or conduct research with Schedule A substances. Practitioners already registered to engage in research of Schedule I substances would not have to obtain a separate registration for Schedule A substances. The Attorney General would be required to grant, deny, or request supplemental information within 60 days of receiving an application; and if supplemental information is requested, the Attorney General would be required to grant or deny registration within 30 days after receiving the requested supplemental information.

CONCERNS WITH H.R. 2851

I. H.R. 2851 Would Give the Attorney General Sweeping Authority to Schedule Any Substance.

H.R. 2851 would give the Attorney General, as likely delegated to the DEA, the sole authority to schedule and, thus, outlaw synthetic analogues based on vaguely-defined standards and set drug equivalencies for sentencing purposes, effectively allowing the Department of Justice to define new criminal offenses to enforce and to set the penalties for violating those offenses. As Michael Collins, Deputy Director of the Drug Policy Alliance, observes, the bill

"gives the Attorney General a ton of power in terms of scheduling drugs and pursuing penalties." [7]

Pursuant to the legislation, the Attorney General would be authorized to permanently place a drug or substance on Schedule A that has a chemical structure and an actual or predicted stimulant, depressant, or hallucinogenic effect on a person that is substantially similar to or greater than the effect of an already-scheduled controlled substance. Critics of the AEA routinely cite the difficulties experienced in proving that an analogue is "substantially similar" in structure or effect to a drug or substance on Schedule I or II.[8] Yet this bill includes the same vague terminology and fails to define or clarify the meaning of "substantially similar."

The predicted effect may be based on just one of the following factors: (1) the chemical structure, structure activity relationships, binding receptor assays, or other relevant scientific information about the substance; (2) the current or relative potential for abuse of the substance, and the clandestine importation, manufacture, or distribution, or diversion from legitimate channels, of the substance; or (3) the capacity of the substance to cause a state of dependence. Despite this troubling authorization to schedule drugs or substances based on such speculation, the language of the bill that outlines the basis on which such predictions may be based is even more concerning. Arguably, the Attorney General would not necessarily be required to establish the predicted effect of a drug or substance based on any of the factors listed in the bill.

While the Attorney General's authority would go largely unchecked, based on an amendment adopted by the Committee, Congress would have the ability to object to the placement of a substance on Schedule A within 180 days of the filing of a scheduling action. Relying on Congress to conduct the analysis that should have been conducted by the agencies, ideally including HHS and also the FDA, is not an acceptable way to address a process in this bill that is flawed in the first place. This congressional override would not afford adequate oversight of the overwhelming amount of power bestowed upon the Attorney General and ensure the reliability of synthetic analogue scheduling. It also fails to provide for binding review of scheduling actions by any agency or authority outside of the DOJ.

Finally, the bill would require judges to sentence offenders convicted of offenses involving analogues or substances not referenced in the Guidelines based on equivalency amounts unilaterally set by the Attorney General. This is particularly problematic because the U.S. Sentencing Commission is currently conducting an extensive study of analogues and synthetic drugs.[9] Without direction from Congress, it is very likely that the Attorney General will not con-

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[7] Christopher Ingram, *Congress is considering a bill that would expand Jeff Sessions's power to escalate the war on drugs,* Wash. Post, June 16, 2017, available at https://www.washingtonpost.com/news/wonk/wp/2017/06/16/congress-is-considering-a-bill-that-would-expand-jeff-sessions-power-to-escalate-the-war-on-drugs/?utm__term=.23fb6ae9f6d6.

[8] *The Dangers of Synthetic Cannabinoids and Stimulants: Hearing Before the S. Caucus on International Narcotics Control,* 112th Cong. (2011) (statement of Joseph T. Rannazzisi, Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration); Deadly Synthetic Drugs—*The Need to Stay Ahead of the Poison Peddlers: Hearing Before the S. Comm. on the Judiciary,* 113th Congress (2016) (statement of Chuck Rosenberg, Acting Administrator, Drug Enforcement Administration).

[9] *See* U.S. Sentencing Comm'n, Transcript of Testimony from Public Hearing: Alternatives to Incarceration Court Programs and Synthetic Drugs (Apr. 18, 2017), http://www.ussc.gov/sites/default/files/pdf/amendment-process/public-hearings-and-meetings/20170418/transcript.pdf.

sider the Commission's consultations with experts, chemists, law enforcement, and practitioners or resulting conclusions. The equivalency tables, which should not be codified in law due to the ever-changing nature of synthetic drugs, would be set without the benefit of the Commission's vital study.

II. H.R. 2851 Would Eliminate Scientific and Medical Analysis of Scheduling Actions.

Proponents of H.R. 2851 argue that there is often not enough information known about newly identified synthetic analogues to quickly schedule them. In an effort to speed up the process of scheduling synthetic analogues, this bill would circumvent the current permanent and temporary inter-agency scheduling processes, allowing the placement of drugs or substances on Schedule A based purely on the speculation of the Attorney General and the DEA. While much of the conversation about synthetic analogues focuses on the chemistry of the substances—from their manufacture to their effect on the human body—this bill would eliminate the long-standing eight-factor analysis of drugs and substances established by the CSA and simply require the Attorney General to consider scheduling recommendations made by HHS. In addition, it would remove HHS's binding authority to halt unjustifiable scheduling actions.

The permanent scheduling process by which drugs are placed on Schedules I, II, III, IV, and V through administrative rulemaking has existed for nearly fifty years. Ultimately, to permanently schedule a drug or substance under the CSA, the Attorney General must find that a drug or substance has the potential for abuse, and then determine in which schedule to place the drug or substance based on the characteristics of the drug or substance. The CSA provides eight factors to consider when determining whether a drug or substance has a potential for abuse, including scientific evidence of the drug or substance's pharmacological effect; the scope, duration, and significance of abuse; and the history and current pattern of abuse. Under the proposed legislation, however, the Attorney General would not be required to examine the potential for abuse or consider the eight factors to permanently place drugs or substances on Schedule A.

Although the DEA, acting under the authority of the Attorney General, is the primary agency responsible for regulating controlled substances under the CSA, HHS performs various vital functions in the scheduling process, several of which are performed by the Food and Drug Administration (FDA). "The legislative history of the CSA is replete with hearings, discussion and statements that the scientific and medical evaluation of DHHS is important and critical to the process." [10] The FDA conducts the scientific and medical evaluations required under the CSA—the eight-factor analysis—while the National Institute on Drug Abuse (NIDA) consults with the FDA and provides concurrent review of the data. The evaluations from the FDA and NIDA form the basis of the HHS recommendation to the DEA, and the resulting medical and sci-

[10] *Scheduling of Drugs Under the Controlled Substances Act: Hearing Before the Subcomm. on Oversight and Investigations of the H. Comm. on Commerce,* 106th Cong. (1999) (prepared statement of Nicholas Reuter, Associate Director for Domestic and International Drug Control, Office of Health Affairs, FDA).

entific evaluations issued by HHS are binding on the DEA. Notably, the CSA mandates that the Attorney General not control the drug or other substance if HHS recommends that a drug or other substance should not be controlled.[11]

As previously discussed, this bill would permit temporary and permanent placement of a drug or substance on Schedule A based on the Attorney General's predictions. H.R. 2851 would allow the Attorney General to make such predictions absent any requirement to consult with or seek input from HHS, the FDA, NIDA, the medical and scientific communities, or other authority outside of the Department of Justice. Scheduling orders would not be subject to scientific review of any kind. The Attorney General would only be required to *consider* recommendations made by the HHS—eliminating the ability of HHS to stop unwarranted scheduling actions.

H.R. 2851 would also establish a diluted version of the existing temporary scheduling processes under the CSA or the AEA. Temporary scheduling was specifically designed to enable the DEA to act in an expeditious manner to avoid an imminent hazard to the public safety.[12] The CSA currently authorizes temporary placement of a drug or substance on Schedule I to avoid an imminent hazard to public safety for up to two years only after the Attorney General demonstrates: (1) the drug's history and current pattern of abuse; (2) the scope, duration and significance of abuse; and (3) what, if any, risk there is to the public health.[13] This three-factor analysis includes consideration of actual abuse; diversion of the drug or substance from legitimate channels; and clandestine importation, manufacture, or distribution of the drug or substance.[14] As previously discussed, a temporarily scheduled drug or substance may be subsequently placed on a schedule permanently only after the requisite medical and scientific eight-factor analysis has been completed by HHS.

H.R. 2851 would eliminate the requirement to analyze the history of a drug's abuse or its potential risk to public health, and instead require a simple finding by the Attorney General that: a drug or substance meets Schedule A criteria; and temporary placement on Schedule A would "assist in preventing abuse or misuse of a drug or other substance"—yet another vague use of terminology within the bill.[15] Following the requisite 30-day notice of intent issued to the public and HHS, any such drug or substance could remain "temporarily" on Schedule A for five years, with the Attorney General having proven very little medically, scientifically, or criminogenically. The lesser burden of proof necessary to place substances temporarily on Schedule A would give the Attorney General wide latitude to schedule countless substances. The subsequent permanent placement under SITSA would require no further analysis, review, or evidence.

Proponents of the bill argue that giving the Attorney General the ability to schedule synthetic analogues temporarily or permanently within thirty days is necessary to speed up the process of outlawing

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[11] 21 U.S.C. § 811(b) (2017).

[12] Drug Enforcement Administration, Dept. of Justice, *Schedules of Controlled Substances: Temporary Placement of Acryl Fentanyl Into Schedule I,* 82 Fed. Reg. 32453 (July 14, 2017).

[13] 21 U.S.C. § 811(h) (2017).

[14] 21 U.S.C. § 811(h)(3) (2017).

[15] Stop the Importation and Trafficking of Synthetic Analogues Act, H.R. 2851, 115th Cong. § 3 (2017).

synthetic analogues and, thus, stop the importation and distribution of such substances quickly. Ms. Ashley testified before the Subcommittee that the process of temporarily scheduling drugs or substances under the CSA typically takes three to four months and permanent placement takes from eighteen months to several years. After praising the great partnership between the scientific staff at DEA and HHS that involves "a day-to-day relationship" and "exchanging information constantly," Ms. Ashley stated incorrectly that the eight-factor analysis would continue to be included in the process of permanently scheduling Schedule A substances under SITSA.

Synthetic analogue abuse undoubtedly presents a potential danger to public health, and law enforcement is experiencing some difficulty in developing an appropriate and coherent response. Nevertheless, Congress must be careful in formulating a response to address the dangers these drugs pose and the issues encountered by law enforcement. Medical and scientific evidence are essential to establish the need to prohibit and, thus, criminalize drugs and substances. HHS should be involved in the evaluation of synthetic analogues to uphold the integrity of the scheduling process. While it might be expedient to shave two or three months from the temporary scheduling process, it is imprudent to completely eliminate medical and scientific analysis and review of drugs and substances from the process.

III. H.R. 2851 Conflicts With the Need to Reform Our Drug Laws.

After four decades of a failed war on drugs, the outcome has remained the same. Based in part on excessive, and often mandatory, minimum penalties in our drug laws, there has been a growing bipartisan movement to reform both the state and federal criminal justice systems in recent years. Unfortunately, the approach of H.R. 2851 runs counter to these efforts to reform these laws. A broad coalition of stakeholders—including the Drug Policy Alliance, the American Civil Liberties Union, the Leadership Conference on Civil and Human Rights, Families Against Mandatory Minimums, the Sentencing Project, Human Rights Watch, and the American Bar Association—have expressed strong objection to H.R. 2851 for several reasons.[16] These groups collectively argue that this legislation undermines the previous progress made to reform the criminal justice system.

For example, the Pew Center's Public Safety Performance Project recently compared data from law enforcement, corrections, and health agencies to evaluate the relationship between imprisonment and the nature and extent of the country's drug problem. The Project reports that "[a]nalysis of the data revealed that there is no statistically significant relationship between state drug offender imprisonment rates and three measures of state drug problems:

[16] *See* Drug Policy Alliance one pager, *S. 1327/H.R. 2851: Stop the Importation and Trafficking of Synthetic Analogues (SITSA) Act of 2017* (2017) [hereinafter Drug Policy Alliance one pager]; see also Letter from coalition of sixty-five civil and human rights, faith, and criminal justice reform organizations, to Rep. Bob Goodlatte, Chairman, H. Comm. on the Judiciary, & Rep. John Conyers, Jr., Ranking Member, H. Comm. on the Judiciary (June 26, 2017) (on file with Democratic staff of the H. Comm. on the Judiciary).

rates of illicit drug use, drug overdose deaths, and drug arrests." [17] With respect to the federal penal system, nearly half of all people in federal prisons in 2015 were serving time for drug offenses.[18] As stated in a letter to the President's Commission on Combating Drug Addiction and the Opioid Crisis, the Project stated that federal prison spending grew exponentially between 1980 and 2013, "without a convincing public safety return." [19]

The 2016 National Drug Threat Assessment suggests that traffickers of synthetic cannabinoids and synthetic cathinones may continue to distribute these popular substances, regardless of their status on the controlled substances list, a premise also expressed by Louis J. Milione, the DEA's Assistant Administrator.[20] Synthetic drugs and substances are inexpensive, easily accessible to both users and suppliers, and, thus, extremely tempting to dealers, traffickers, and users. As explained at a Subcommittee hearing held last year, the profit margin for these substances is considerably high.[21] The Pew Project suggests that this legislation could serve only to force the use of synthetic drugs underground, driving profitability up and encouraging dealers, traffickers, and manufacturers to continue to produce the drugs despite breaking the law.[22] Based on the lessons learned from the crack era to today, a flawed and rushed effort to apply criminal penalties for synthetic analogues, H.R. 2851 will have very little effect, if any at all, on the supply or demand for these drugs.

Despite the abundant evidence supporting the need to curtail the U.S. criminal justice system's reliance on incarceration, particularly with respect to drug offenses, this bill would sweep more individuals into the federal criminal justice system and allow law enforcement to target substances of which very little is known scientifically about their harms or benefits. The Subcommittee approved an amendment introduced by Subcommittee Chairman Jim Sensenbrenner (R–WI) that removed mandatory minimum imprisonment penalties from the bill. Nevertheless, mandatory minimum terms of supervised release remain and the penalties proposed in the bill would still subject offenders to potentially lengthy sentences. James C. Duff, Secretary of the Judicial Conference of the United States, conveyed the Conference's objection to the mandatory minimum terms of supervised release in a letter to Subcommittee Members.[23] He stated, "Mandatory minimum sentences—including mandatory minimum term of supervised release—waste valuable taxpayer dollars, create injustice in sen-

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[17] Letter from Adam Gelb, Pew Charitable Trusts, Public Safety Performance Project, to the Honorable Chris Christie, President's Commission on Combating Drug Addiction and the Opioid Crisis (June 19, 2017) (on file with H. Comm. on the Judiciary Democratic staff) [hereinafter Pew Letter].

[18] E. Carson & E. Anderson, E., Prisoners in 2015, U.S. Dep't of Justice, Bureau of Justice Statistics (Dec. 2016), *available at https://www.bjs.gov/content/pub/pdf/p15.pdf.*

[19] Pew Letter.

[20] U.S. Department of Justice, Drug Enforcement Administration, *National Drug Threat Assessment,* (Nov. 2016); *Fentanyl: The Next Wave of the Opioid Crisis: Hearing Before the Subcommittee on Oversight and Investigations of the H. Comm. on the Judiciary,* 115th Congress (2017) (statement of Louis J. Milione, Assistant Administrator, DEA).

[21] *Synthetic Drugs, Real Danger: Hearing Before the Subcomm. on Crime, Terrorism, Homeland Security, and Investigations of the H. Comm. on the Judiciary,* 114th Cong. (2016).

[22] *Id.*

[23] Letter from James C. Duff, Secretary, Judicial Conference of the United States, to Ranking Member Shelia Jackson Lee, Subcomm. on Crime, Terrorism, Homeland Security, and Investigations, H. Comm. on the Judiciary (July 7, 2017) (on file with H. Comm. on the Judiciary Democratic Staff).

tencing, undermine guideline sentencing, and ultimately foster a lack of confidence in the criminal justice system."[24] Congress should "avoid the costs associated with mandatory minimum sentences" and restore sentencing discretion to district judges, who are in the best position to impose punishments that are appropriate and just."[25]

Furthermore, while the bill excludes prosecution for simple possession of synthetic analogues placed on Schedule A, it nevertheless fails to set threshold amounts for manufacture, distribution, importation, or exportation offenses involving synthetic analogues. Thus, even possession of small amounts of the drugs could, in some cases, lead to prosecutors bringing federal charges.

IV. H.R. 2851 Could Stifle Legitimate Synthetic Analogue Research.

"Critics are worried that the bill's language could be used to justify bans on all manner of substances that are not particularly lethal or dangerous."[26] The bill has the potential to undermine and stifle the research and development of therapeutic uses of synthetic compounds, such as opioids. This result is counterproductive from the standpoint of public health. For instance, federal law has already unnecessarily impeded scientific and medical research into the medical uses of marijuana.

Although Chairman Goodlatte offered a substitute amendment, which was adopted, that would exempt researchers who hold a Schedule I registration from having to obtain a separate registration for Schedule A substances or submit a protocol review, only a small number of researchers currently hold a Schedule I registration. Many more researchers hold Schedule II registrations and, thus, would not benefit from this narrow improvement to the bill.

CONCLUSION

H.R. 2851 would unwisely and unnecessarily grant broad powers to the Attorney General—without the benefit of adequate scientific and medical research—to expand the application of criminal penalties with respect to analogue synthetic drugs. Although we must do more to combat the abuse of synthetic drugs, including opioids, this bill is an extreme and unwise measure. Therefore, we are unable to support this bill and must respectfully dissent.

MR. NADLER.
MS. LOFGREN.
MS. JACKSON LEE.
MR. COHEN.
MR. JOHNSON, JR.
MR. JEFFRIES.
MS. JAYAPAL.

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[24] *Id.*
[25] *Id.*
[26] *Id.*