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S. 1327

To amend the Controlled Substances Act to clarify how controlled substance analogues are to be regulated, and for other purposes.

IN THE SENATE OF THE UNITED STATES

JUNE 8, 2017

Mr. GRASSLEY (for himself and Mrs. FEINSTEIN) introduced the following bill; which was read twice and referred to the Committee on the Judiciary

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A BILL

To amend the Controlled Substances Act to clarify how controlled substance analogues are to be regulated, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

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 pro-

ceedings 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.''.

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 author-

ized 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 for any term of years or for 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 a term of imprisonment for any term of years or for life, 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—

(1) in subsection (f), in the undesignated matter following paragraph (5)—

(A) by inserting ''or A'' after ''schedule I'' each place it appears; and

(B) by adding at the end the following: ''A separate registration for engaging in research with a controlled substance in schedule A for practitioners already registered under this part to engage in research with controlled substances in schedule I shall not be required. The Sec-

retary shall determine the merits of the research protocol submitted by the practitioner registering to engage in research with a controlled substance in schedule A, and the Attorney General may deny or revoke the registration only on a ground specified in section 304.'';

and

(2) 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, sci-

entific, 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.''.

(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. CLARIFICATION OF THE DEFINITION OF CONTROLLED SUBSTANCE ANALOGUE UNDER THE ANALOGUE ENFORCEMENT ACT.

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. 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.

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