115TH CONGRESS 2D SESSION

H.R. 2851

AN ACT

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

- 1 Be it enacted by the Senate and House of Representa-
- 2 tives of the United States of America in Congress assembled,

1 SECTION 1. SHORT TITLE.

2	This Act may be cited as the "Stop the Importation				
3	and Trafficking of Synthetic Analogues Act of 2017" or				
4	the "SITSA Act".				
5	SEC. 2. ESTABLISHMENT OF SCHEDULE A.				
6	Section 202 of the Controlled Substances Act (21				
7	U.S.C. 812) is amended—				
8	(1) in subsection (a), by striking "five schedules				
9	of controlled substances, to be known as schedules I,				
10	II, III, IV, and V" and inserting "six schedules of				
11	controlled substances, to be known as schedules I,				
12	II, III, IV, V, and A'';				
13	(2) in subsection (b), by adding at the end the				
14	following:				
15	"(6) Schedule A.—				
16	"(A) IN GENERAL.—The drug or substance—				
17	"(i) has—				
18	"(I) a chemical structure that is sub-				
19	stantially similar to the chemical structure				
20	of a controlled substance in schedule I, II,				
21	III, IV, or V; and				
22	"(II) an actual or predicted stimulant,				
23	depressant, or hallucinogenic effect on the				
24	central nervous system that is substantially				
25	similar to or greater than the stimulant,				
26	depressant, or hallucinogenic effect on the				

1	central nervous system of a controlled sub-
2	stance in schedule I, II, III, IV, or V; and
3	"(ii) is not—
4	"(I) listed or otherwise included in
5	any other schedule in this section or by
6	regulation of the Attorney General; and
7	"(II) with respect to a particular per-
8	son, subject to an exemption that is in ef-
9	fect for investigational use, for that person,
10	under section 505 of the Federal Food,
11	Drug, and Cosmetic Act (21 U.S.C. 355)
12	to the extent conduct with respect to such
13	substance is pursuant to such exemption.
14	"(B) Predicted stimulant, depressant, or
15	HALLUCINOGENIC EFFECT.—For purpose of this
16	paragraph, a predicted stimulant, depressant, or hal-
17	lucinogenic effect on the central nervous system may
18	be based on—
19	"(i) the chemical structure and—
20	"(I) the structure activity relation-
21	ships; or
22	"(II) binding receptor assays and
23	other relevant scientific information about
24	the substance;

1	"(ii)(I) the current or relative potential for
2	abuse of the substance; and
3	"(II) the clandestine importation, manu-
4	facture, or distribution, or diversion from legiti-
5	mate channels, of the substance; or
6	"(iii) the capacity of the substance to
7	cause a state of dependence, including physical
8	or psychological dependence that is similar to or
9	greater than that of a controlled substance in
10	schedule I, II, III, IV, or V."; and
11	(3) in subsection (c), in the matter preceding
12	schedule I, by striking "IV, and V" and inserting
13	"IV, V, and A".
14	SEC. 3. TEMPORARY AND PERMANENT SCHEDULING OF
15	SCHEDULE A SUBSTANCES.
16	Section 201 of the Controlled Substances Act (21
17	U.S.C. 811) is amended by adding at the end the fol-
18	lowing:
19	"(k) Temporary and Permanent Scheduling of
20	SCHEDULE A SUBSTANCES.—
21	"(1) The Attorney General may issue a tem-
22	porary order adding a drug or substance to schedule
23	A if the Attorney General finds that—

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1	"(A) the drug or other substance satisfies
2	the criteria for being considered a schedule A
3	substance; and
4	"(B) adding such drug or substance to
5	schedule A will assist in preventing abuse of the
6	drug or other substance.
7	"(2) A temporary scheduling order issued under
8	paragraph (1) shall not take effect until 30 days
9	after the date of the publication by the Attorney
10	General of a notice in the Federal Register of the in-
11	tention to issue such order and the grounds upon
12	which such order is to be issued. The temporary
13	scheduling order shall expire not later than 5 years
14	after the date it becomes effective, except that the
15	Attorney General may, during the pendency of pro-
16	ceedings under paragraph (5), extend the temporary
17	scheduling order for up to 180 days.
18	"(3) A temporary scheduling order issued under
19	paragraph (1) shall be vacated upon the issuance of
20	a permanent order issued under paragraph (5) with

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

regard to the same substance, or upon the subse-

quent issuance of any scheduling order under this

section.

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"(5)(A) Beginning no earlier than 3 years after issuing an order temporarily scheduling a drug or other substance under this subsection, 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 controlled substance in schedule A under this subsection, except as provided in subparagraph (B).

"(B) If the Secretary has determined, based on relevant scientific studies and necessary data requested by the Secretary and gathered by the Attorney General, that a drug or other substance that has been temporarily placed in schedule A does not have sufficient potential for abuse to warrant control in any schedule, and so advises the Attorney General in writing, the Attorney General may not issue a permanent scheduling order under subparagraph (A) and shall, within 30 days of receiving the Secretary's advice issue an order immediately terminating the temporary scheduling order.

"(6) Before initiating proceedings under paragraph (1), the Attorney General shall transmit notice of a temporary order proposed to be issued to the Secretary of Health and Human Services. In

- 1 issuing an order under paragraph (1), the Attorney
- 2 General shall take into consideration any comments
- 3 submitted by the Secretary of Health and Human
- 4 Services in response to a notice transmitted pursu-
- 5 ant to this paragraph.
- 6 "(7) On the date of the publication of a notice
- 7 in the Federal Register pursuant to paragraph (2),
- 8 the Attorney General shall transmit the same notice
- 9 to Congress. The temporary scheduling order shall
- take effect according to paragraph (2), except that
- the temporary scheduling order may be disapproved
- by an Act of Congress within 180 days from the
- date of publication of the notice in the Federal Reg-
- 14 ister.".
- 15 SEC. 4. PENALTIES.
- 16 (a) Controlled Substances Act.—The Con-
- 17 trolled Substances Act (21 U.S.C. 801 et seq.) is amend-
- 18 ed—
- 19 (1) in section 401(b)(1) (21 U.S.C. 841(b)(1)),
- by adding at the end the following:
- 21 "(F)(i) In the case of any controlled substance in
- 22 schedule A, such person shall be sentenced to a term of
- 23 imprisonment of not more than 10 years and if death or
- 24 serious bodily injury results from the use of such sub-
- 25 stance shall be sentenced to a term of imprisonment of

- 1 not more than 15 years, a fine not to exceed the greater
- 2 of that authorized in accordance with the provisions of
- 3 title 18, United States Code, or \$500,000 if the defendant
- 4 is an individual or \$2.5 million if the defendant is other
- 5 than an individual, or both.
- 6 "(ii) If any person commits such a violation after a
- 7 prior conviction for a felony drug offense has become final,
- 8 such person shall be sentenced to a term of imprisonment
- 9 of not more than 20 years and if death or serious bodily
- 10 injury results from the use of such substance shall be sen-
- 11 tenced to a term of imprisonment of not more than 30
- 12 years, a fine not to exceed the greater of twice that author-
- 13 ized in accordance with the provisions of title 18, United
- 14 States Code, or \$1 million if the defendant is an individual
- 15 or \$5 million if the defendant is other than an individual,
- 16 or both.
- 17 "(iii) Any sentence imposing a term of imprisonment
- 18 under this subparagraph shall, in the absence of such a
- 19 prior conviction, impose a term of supervised release of
- 20 not less than 2 years in addition to such term of imprison-
- 21 ment and shall, if there was such a prior conviction, im-
- 22 pose a term of supervised release of not less than 4 years
- 23 in addition to such term of imprisonment.";
- 24 (2) in section 403(a) (21 U.S.C. 843(a))—

1	(A) in paragraph (8), by striking "or" at					
2	the end;					
3	(B) in paragraph (9), by striking the pe-					
4	riod at the end and inserting "; or"; and					
5	(C) by inserting after paragraph (9) the					
6	following:					
7	"(10) to export a substance in violation of the					
8	controlled substance laws of the country to which					
9	the substance is exported."; and					
10	(3) in section 404 (21 U.S.C. 844), by inserting					
11	after subsection (a) the following:					
12	"(b) A person shall not be subject to a criminal or					
13	civil penalty under this title or under any other Federal					
14	law solely for possession of a schedule A controlled sub-					
15	stance.".					
16	(b) Controlled Substances Import and Export					
17	Act.—Section 1010(b) of the Controlled Substances Im-					
18	port and Export Act (21 U.S.C. 960(b)) is amended by					
19	adding at the end the following:					
20	"(8) In the case of a violation under subsection (a)					
21	involving a controlled substance in schedule A, the person					
22	committing such violation shall be sentenced to a term of					
23	imprisonment of not more than 20 years and if death or					
24	serious bodily injury results from the use of such sub-					
25	stance shall be sentenced to a term of imprisonment of					

not more than life, a fine not to exceed the greater of that 2 authorized in accordance with the provisions of title 18, 3 United States Code, or \$1 million if the defendant is an 4 individual or \$5 million if the defendant is other than an individual, or both. If any person commits such a violation 6 after a prior conviction for a felony drug offense has become final, such person shall be sentenced to a term of 8 imprisonment of not more than 30 years and if death or serious bodily injury results from the use of such sub-10 stance shall be sentenced to not more than life imprisonment, a fine not to exceed the greater of twice that author-12 ized in accordance with the provisions of title 18, United States Code, or \$2 million if the defendant is an individual 14 or \$10 million if the defendant is other than an individual, 15 or both. Notwithstanding section 3583 of title 18, United States Code, any sentence imposing a term of imprison-16 ment under this paragraph shall, in the absence of such 17 18 a prior conviction, impose a term of supervised release of not less than 3 years in addition to such term of imprison-19 ment and shall, if there was such a prior conviction, im-20 21 pose a term of supervised release of not less than 6 years in addition to such term of imprisonment. Notwith-23 standing 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

- 1 under the provisions of this paragraph which provide for
- 2 a mandatory term of imprisonment if death or serious
- 3 bodily injury results.".
- 4 SEC. 5. FALSE LABELING OF SCHEDULE A CONTROLLED
- 5 SUBSTANCES.
- 6 (a) IN GENERAL.—Section 305 of the Controlled
- 7 Substances Act (21 U.S.C. 825) is amended by adding at
- 8 the end the following:
- 9 "(f) False Labeling of Schedule A Con-
- 10 TROLLED 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 sched-
- 15 ule A substance, unless the substance or product
- bears a label clearly identifying a schedule A sub-
- stance or product containing a schedule A substance
- by the nomenclature used by the International
- 19 Union of Pure and Applied Chemistry (IUPAC).
- 20 "(2)(A) A product described in subparagraph
- (B) is exempt from the International Union of Pure
- and Applied Chemistry nomenclature requirement of
- 23 this subsection if such product is labeled in the man-
- 24 ner required under the Federal Food, Drug, and
- 25 Cosmetic Act.

1	"(B) A product is described in this subpara-				
2	graph if the product—				
3	"(i) is the subject of an approved applica-				
4	tion as described in section 505(b) or (j) of the				
5	Federal Food, Drug, and Cosmetic Act; or				
6	"(ii) is exempt from the provisions of sec-				
7	tion 505 of such Act relating to new drugs be-				
8	cause—				
9	"(I) it is intended solely for investiga-				
10	tional use as described in section 505(i) of				
11	such Act; and				
12	"(II) such product is being used ex-				
13	clusively for purposes of a clinical trial				
14	that is the subject of an effective investiga-				
15	tional new drug application.".				
16	(b) Penalties.—Section 402 of the Controlled Sub-				
17	stances Act (21 U.S.C. 842) is amended—				
18	(1) in subsection (a)(16), by inserting "or sub-				
19	section (f)" after "subsection (e)"; and				
20	(2) in subsection (c)(1)(D), by inserting "or a				
21	schedule A substance" after "anabolic steroid".				

1	SEC. 6. REGISTRATION REQUIREMENTS FOR HANDLERS OF
2	SCHEDULE A SUBSTANCES.
3	(a) Controlled Substances Act.—Section 303 of
4	the Controlled Substances Act (21 U.S.C. 823) is amend-
5	ed by adding at the end the following:
6	``(k)(1) The Attorney General shall register an appli-
7	cant to manufacture schedule A substances if—
8	"(A) the applicant demonstrates that the sched-
9	ule A substances will be used for research, analyt-
10	ical, or industrial purposes approved by the Attorney
11	General; and
12	"(B) the Attorney General determines that such
13	registration is consistent with the public interest and
14	with the United States obligations under inter-
15	national treaties, conventions, or protocols in effect
16	on the date of enactment of this subsection.
17	"(2) In determining the public interest under para-
18	graph (1)(B), the Attorney General shall consider—
19	"(A) maintenance of effective controls against
20	diversion of particular controlled substances and any
21	controlled substance in schedule A compounded
22	therefrom into other than legitimate medical, sci-
23	entific, research, or industrial channels, by limiting
24	the importation and bulk manufacture of such con-
25	trolled substances to a number of establishments
26	which can produce an adequate and uninterrupted

1	supply of these substances under adequately com-
2	petitive conditions for legitimate medical, scientific,
3	research, and industrial purposes;
4	"(B) compliance with applicable State and local
5	law;
6	"(C) promotion of technical advances in the art
7	of manufacturing substances described in subpara-
8	graph (A) and the development of new substances;
9	"(D) prior conviction record of applicant under
10	Federal and State laws relating to the manufacture,
11	distribution, or dispensing of substances described in
12	paragraph (A);
13	"(E) past experience in the manufacture of con-
14	trolled substances, and the existence in the establish-
15	ment of effective control against diversion; and
16	"(F) such other factors as may be relevant to
17	and consistent with the public health and safety.
18	"(3) If an applicant is registered to manufacture con-
19	trolled substances in schedule I or II under subsection (a),
20	the applicant shall not be required to apply for a separate
21	registration under this subsection.
22	"(l)(1) The Attorney General shall register an appli-
23	cant to distribute schedule A substances—
24	"(A) if the applicant demonstrates that the
25	schedule A substances will be used for research, ana-

1 lytical, or industrial purposes approved by the Attor-2 ney General; and "(B) unless the Attorney General determines 3 4 that the issuance of such registration is inconsistent 5 with the public interest. 6 "(2) In determining the public interest under para-7 graph (1)(B), the Attorney General shall consider— "(A) maintenance of effective control against 8 9 diversion of particular controlled substances into 10 other than legitimate medical, scientific, and indus-11 trial channels; 12 "(B) compliance with applicable State and local 13 law; 14 "(C) prior conviction record of applicant under 15 Federal or State laws relating to the manufacture, 16 distribution, or dispensing of substances described in 17 subparagraph (A); 18 "(D) past experience in the distribution of con-19 trolled substances; and "(E) such other factors as may be relevant to 20 21 and consistent with the public health and safety. 22 "(3) If an applicant is registered to distribute a con-23 trolled substance in schedule I or II under subsection (b), the applicant shall not be required to apply for a separate registration under this subsection.

- 1 "(m)(1)(A) Not later than 90 days after the date on
- 2 which a substance is placed in schedule A, any practitioner
- 3 who was engaged in research on the substance before the
- 4 placement of the substance in schedule A and any manu-
- 5 facturer or distributor who was handling the substance be-
- 6 fore the placement of the substance in schedule A shall
- 7 register with the Attorney General.
- 8 "(B)(i) If an applicant described in subparagraph (A)
- 9 is registered pursuant to subsection (f) to conduct re-
- 10 search with a controlled substance in schedule I or II on
- 11 the date on which another substance is placed in schedule
- 12 A, the applicant may, subject to clause (iii), conduct re-
- 13 search with that other controlled substance in schedule A
- 14 while the application for registration pursuant to subpara-
- 15 graph (A) is pending.
- 16 "(ii) If an applicant described in subparagraph (A)
- 17 is registered pursuant to subsection (f) as described in
- 18 clause (i) to conduct research with a controlled substance
- 19 in schedule III, IV, or V on the date on which another
- 20 substance is placed in schedule A, the applicant may, sub-
- 21 ject to clause (iii), conduct research with that other con-
- 22 trolled substance in schedule A while the application for
- 23 registration pursuant to subparagraph (A) is pending,
- 24 provided the substance for which the applicant is reg-
- 25 istered to conduct research is in the same schedule as, or

- 1 a less-restricted schedule than, the controlled substance
- 2 whose similarity in chemical structure and actual or pre-
- 3 dicted effect to the controlled substance in schedule A
- 4 formed the basis for placement of the substance in sched-
- 5 ule A, as set forth in the order published in the Federal
- 6 Register placing the substance in schedule A.
- 7 "(iii) The permission to conduct research pursuant
- 8 to clause (i) or clause (ii) is conditional on the applicant's
- 9 complying with the registration and other requirements
- 10 for controlled substances in schedule A.
- 11 "(iv) This subparagraph does not apply to applicants
- 12 registered pursuant to subsection (f) whose authorization
- 13 to conduct research with any controlled substances is lim-
- 14 ited to doing so as a coincident activity pursuant to appli-
- 15 cable regulations of the Attorney General.
- 16 "(2)(A) Not later than 60 days after the date on
- 17 which the Attorney General receives an application for
- 18 registration to conduct research on a schedule A sub-
- 19 stance, the Attorney General shall—
- 20 "(i) grant, or initiate proceedings under section
- 21 304(c) to deny, the application; or
- "(ii) request supplemental information from the
- applicant.
- 24 "(B) Not later than 30 days after the date on which
- 25 the Attorney General receives supplemental information

- 1 requested under subparagraph (A)(ii) in connection with
- 2 an application described in subparagraph (A), the Attor-
- 3 ney General shall grant or deny the application.
- 4 "(n)(1) The Attorney General shall register a sci-
- 5 entific investigator or a qualified research institution to
- 6 conduct research with controlled substances in schedule A
- 7 in accordance with this subsection. In evaluating applica-
- 8 tions for such registration, the Attorney General shall
- 9 apply the criteria set forth in subsection (f) of this section
- 10 that apply to practitioners seeking a registration to con-
- 11 duct research with a schedule I controlled substance, ex-
- 12 cept that the applicant shall not be required to submit a
- 13 research protocol.
- 14 "(2) If the applicant is not currently registered under
- 15 subsection (f) to conduct research with a schedule I con-
- 16 trolled substance, the Attorney General shall refer the ap-
- 17 plication to the Secretary, who shall determine whether
- 18 the applicant will be engaged in bona fide research and
- 19 is qualified to conduct such research. The 60-day period
- 20 under subsection (m)(2)(A) shall be tolled during the pe-
- 21 riod beginning on the date on which the Attorney General
- 22 refers an application to the Secretary under this para-
- 23 graph, and ending on the date on which the Secretary sub-
- 24 mits a determination related to such referral to the Attor-
- 25 ney General.

- 1 "(3) An applicant who meets the criteria under sub-
- 2 section (m)(1)(B) with respect to a particular schedule A
- 3 controlled substance shall be considered qualified to con-
- 4 duct research with that substance. The Attorney General
- 5 shall modify such applicant's registration to include such
- 6 schedule A controlled substance in accordance with this
- 7 paragraph. The applicant shall notify the Attorney Gen-
- 8 eral of his intent to conduct research with a controlled
- 9 substance in schedule A. Upon receiving such notification,
- 10 the Attorney General shall modify the practitioner's exist-
- 11 ing registration to authorize research with schedule A con-
- 12 trolled substances, unless the Attorney General determines
- 13 that the registration modification would be inconsistent
- 14 with the public interest based on the criteria of subsection
- 15 (f).
- 16 "(4) Registrations issued under this subsection to a
- 17 qualified research institution will apply to all agents and
- 18 employees of that institution acting within the scope of
- 19 their professional practice.
- 20 "(5) At least 30 days prior to conducting any re-
- 21 search with a controlled substance in schedule A, the reg-
- 22 istrant shall provide the Attorney General with written no-
- 23 tification of the following:
- 24 "(A) The name of and drug code for each sub-
- stance.

- 1 "(B) The name of each individual with access 2 to each substance.
- 3 "(C) The amount of each substance.
- 4 "(D) Other similar information the Attorney
- 5 General may require.
- 6 "(6) The quantity of a schedule A controlled sub-
- 7 stance possessed by a person registered under this sub-
- 8 section shall be appropriate for the research being con-
- 9 ducted, subject to the additional limitations set forth in
- 10 this paragraph. To reduce the risk of diversion, the Attor-
- 11 ney General may establish limitations on the quantity of
- 12 schedule A controlled substances that may be manufac-
- 13 tured or possessed for purposes of research under this sub-
- 14 section and shall publish such limitations on the website
- 15 of the Drug Enforcement Administration. A person reg-
- 16 istered under this subsection may, based on legitimate re-
- 17 search needs, apply to the Attorney General to manufac-
- 18 ture or possess an amount greater than that so specified
- 19 by the Attorney General. The Attorney General shall
- 20 specify the manner in which such applications shall be
- 21 submitted. The Attorney General shall act on an applica-
- 22 tion filed under this subparagraph within 30 days of re-
- 23 ceipt of such application. If the Attorney General fails to
- 24 act within 30 days, the registrant shall be allowed to man-
- 25 ufacture and possess up to the amount requested. The At-

- 1 torney General shall have the authority to reverse the in-
- 2 crease for cause.
- 3 "(7) The Attorney General shall by regulation specify
- 4 the manner in which applications for registration under
- 5 this subsection shall be submitted.
- 6 "(8) Registrants authorized under this subsection
- 7 may manufacture and possess schedule A controlled sub-
- 8 stances up to the approved amounts only for use in their
- 9 own research setting or institution. Manufacturing for use
- 10 in any other setting or institution shall require a manufac-
- 11 turer's registration under section 303(a).".
- 12 (b) Controlled Substances Import and Export
- 13 Act.—Section 1008 of the Controlled Substances Import
- 14 and Export Act (21 U.S.C. 958) is amended by adding
- 15 at the end the following:
- 16 "(j)(1) The Attorney General shall register an appli-
- 17 cant to import or export a schedule A substance if—
- 18 "(A) the applicant demonstrates that the sched-
- 19 ule A substances will be used for research, analyt-
- 20 ical, or industrial purposes approved by the Attorney
- 21 General; and
- 22 "(B) the Attorney General determines that such
- registration is consistent with the public interest and
- with the United States obligations under inter-

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1
        national treaties, conventions, or protocols in effect
 2
        on the date of enactment of this subsection.
 3
        "(2) In determining the public interest under para-
   graph (1)(B), the Attorney General shall consider the fac-
 5
   tors described in subparagraphs (A) through (F) of sec-
 6
   tion 303(k)(2).
        "(3) If an applicant is registered to import or export
 7
 8
    a controlled substance in schedule I or II under subsection
 9
    (a), the applicant shall not be required to apply for a sepa-
   rate registration under this subsection.".
10
   SEC. 7. ADDITIONAL CONFORMING AMENDMENTS.
12
        (a) Controlled Substances Act.—The Con-
   trolled Substances Act (21 U.S.C. 801 et seq.) is amend-
   ed—
14
15
             (1) in section 303(c) (21 U.S.C. 823(c))—
                  (A) by striking "subsections (a) and (b)"
16
             and inserting "subsection (a), (b), (k), or (l)";
17
18
             and
19
                  (B) by striking "schedule I or II" and in-
20
             serting "schedule I, II, or A";
21
             (2) in section 306 (21 U.S.C. 826)—
22
                  (A) in subsection (a), in the first sentence,
             by striking "schedules I and II" and inserting
23
             "schedules I, II, and A";
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1	(B) in subsection (b), in the second sen-
2	tence, by striking "schedule I or II" and insert-
3	ing "schedule I, II, or A";
4	(C) in subsection (c), in the first sentence,
5	by striking "schedules I and II" and inserting
6	"schedules I, II, and A";
7	(D) in subsection (d), in the first sentence,
8	by striking "schedule I or II" and inserting
9	"schedule I, II, or A";
10	(E) in subsection (e), in the first sentence,
11	by striking "schedule I or II" and inserting
12	"schedule I, II, or A"; and
13	(F) in subsection (f), in the first sentence,
14	by striking "schedules I and II" and inserting
15	"schedules I, II, and A";
16	(3) in section 308(a) (21 U.S.C. 828(a)), by
17	striking "schedule I or II" and inserting "schedule
18	I, II, or A'';
19	(4) in section 402(b) (21 U.S.C. 842(b)), in the
20	matter preceding paragraph (1), by striking "sched-
21	ule I or II" and inserting "schedule I, II, or A";
22	(5) in section 403(a)(1) (21 U.S.C. 843(a)(1)),
23	by striking "schedule I or II" and inserting "sched-
24	ule I, II, or A"; and

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1
             (6) in section 511(f) (21 U.S.C. 881(f)), by
 2
        striking "schedule I or II" each place it appears and
 3
        inserting "schedule I, II, or A".
 4
        (b) Controlled Substances Import Export
 5
    ACT.—The Controlled Substances Import and Export Act
 6
    (21 U.S.C. 951 et seg.) is amended—
 7
             (1) in section 1002(a) (21 U.S.C. 952(a))—
 8
                  (A) in the matter preceding paragraph (1),
 9
             by striking "schedule I or II" and inserting
             "schedule I, II, or A"; and
10
11
                  (B) in paragraph (2), by striking "sched-
12
             ule I or II" and inserting "schedule I, II, or
13
             A'';
14
             (2) in section 1003 (21 U.S.C. 953)—
15
                  (A) in subsection (c), in the matter pre-
16
             ceding paragraph (1), by striking "schedule I or
17
             II" and inserting "schedule I, II, or A"; and
18
                  (B) in subsection (d), by striking "schedule
19
             I or II" and inserting "schedule I, II, or A";
20
             (3) in section 1004(1) (21 U.S.C. 954(1)), by
        striking "schedule I" and inserting "schedule I or
21
22
        A'';
23
             (4) in section 1005 (21 U.S.C. 955), by striking
24
        "schedule I or II" and inserting "schedule I, II, or
25
        A"; and
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             (5) in section 1009(a) (21 U.S.C. 959(a)), by
 2
        striking "schedule I or II" and inserting "schedule
 3
        I, II, or A".
 4
   SEC. 8. CONTROLLED SUBSTANCE ANALOGUES.
 5
        Section 102 of the Controlled Substances Act (21)
 6
   U.S.C. 802) is amended—
             (1) in paragraph (6), by striking "or V" and in-
 7
        serting "V, or A";
 8
 9
             (2) in paragraph (14)—
                  (A) by striking "schedule I(c) and" and in-
10
11
             serting "schedule I(c), schedule A, and"; and
12
                  (B) by striking "schedule I(c)," and insert-
13
             ing "schedule I(c) and schedule A,"; and
14
             (3) in paragraph (32)(A), by striking "(32)(A)"
15
        and all that follows through clause (iii) and inserting
16
        the following:
        "(32)(A) Except as provided in subparagraph (C),
17
18
   the term 'controlled substance analogue' means a sub-
19
    stance whose chemical structure is substantially similar to
20
   the chemical structure of a controlled substance in sched-
21
   ule I or II—
22
             "(i) which has a stimulant, depressant, or hal-
23
        lucinogenic effect on the central nervous system that
24
        is substantially similar to or greater than the stimu-
25
        lant, depressant, or hallucinogenic effect on the cen-
```

- tral 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

10 SEC. 9. RULES OF CONSTRUCTION.

9

Nothing in this Act, or the amendments made by this

controlled substance in schedule I or II.".

- 12 Act, may be construed to limit—
- 13 (1) the prosecution of offenses involving con-
- trolled substance analogues under the Controlled
- 15 Substances Act (21 U.S.C. 801 et seq.); or
- 16 (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
- 20 U.S.C. 811) that are in effect on the day before the
- 21 date of enactment of this Act.

22 SEC. 10. STUDY BY COMPTROLLER GENERAL.

- Not later than 2 years after the date of enactment
- 24 of this Act, the Comptroller General of the United States
- 25 shall complete a study and submit a report to the Commit-

- 1 tees on the Judiciary of the House of Representatives and
- 2 of the Senate regarding the costs associated with the
- 3 amendments made by section 4, including—
- 4 (1) the annual amounts expended by Federal
- 5 agencies in carrying out the amendments;
- 6 (2) the costs associated with arrests, trials, con-7 victions, imprisonment, or imposition of other sanc-
- 8 tions in accordance with the amendments; and
- 9 (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.
- 13 SEC. 11. REPORT ON CONTROLLED SUBSTANCE ANA-
- 14 LOGUES SOLD BY MEANS OF THE INTERNET.
- Not later than 1 year after the date of the enactment
- 16 of this Act, and annually thereafter, the Administrator of
- 17 the Drug Enforcement Administration shall make publicly
- 18 available on the website of the Drug Enforcement Admin-
- 19 istration a report on, for the previous year, the lawful and
- 20 unlawful sale of controlled substance analogues (as defined
- 21 in section 102 of the Controlled Substances Act (21
- 22 U.S.C. 802)) by means of the Internet, including the fol-
- 23 lowing information:

1 (1) The types of controlled substance analogues 2 that were sold, and the number of sales for each 3 such substance. 4 (2) The name of each person, entity, or Inter-5 net site, whether in the United States or abroad, 6 that knowingly or intentionally delivers, distributes, 7 or dispenses, or offers or attempts to deliver, dis-8 tribute, or dispense, a controlled substance analogue 9 by means of the Internet, whether lawfully or unlaw-10 fully. 11 (3) An estimate of the total revenue for all of 12 the vendors described in paragraph (2) for all of the 13 sales described in paragraph (1). 14 SEC. 12. CONTROLLED SUBSTANCE ANALOGUES. 15 Section 203 of the Controlled Substances Act (21 U.S.C. 813) is amended— 16 (1) by striking "A controlled" and inserting 17 "(a) IN GENERAL.—A controlled"; and 18 19 (2) by adding at the end the following: 20 "(b) Determination.—In determining whether a 21 controlled substance analogue was intended for human 22 consumption under subsection (a), the following factors 23 may be considered, along with any other relevant factors: 24 "(1) The marketing, advertising, and labeling

of the substance.

25

- 1 "(2) The known efficacy or usefulness of the 2 substance for the marketed, advertised or labeled 3 purpose.
- "(3) The difference between the price at which the substance is sold and the price at which the substance it is purported to be or advertised as is normally sold.
- 8 "(4) The diversion of the substance from legiti-9 mate channels and the clandestine importation, man-10 ufacture, or distribution of the substance.
 - "(5) Whether the defendant knew or should have known the substance was intended to be consumed by injection, inhalation, ingestion, or any other immediate means.
- "(6) Any controlled substance analogue that is manufactured, formulated, sold, distributed, or marketed with the intent to avoid the provisions of existing drug laws.
- "(c) Limitation.—For purposes of this section, evi-20 dence that a substance was not marketed, advertised, or 21 labeled for human consumption, by itself, shall not be suf-

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- 1 ficient to establish that the substance was not intended
- 2 for human consumption.".

Passed the House of Representatives June 15, 2018. Attest:

Clerk.

115TH CONGRESS H. R. 2851

AN ACT

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