

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

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 and—

“(I) the structure activity relationships; or

“(II) binding receptor assays and other relevant scientific information about 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—

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
21 regard to the same substance, or upon the subse-
22 quent issuance of any scheduling order under this
23 section.

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

1 “(5)(A) Beginning no earlier than 3 years after
2 issuing an order temporarily scheduling a drug or
3 other substance under this subsection, the Attorney
4 General may, by rule, issue a permanent order add-
5 ing a drug or other substance to schedule A if such
6 drug or substance satisfies the criteria for being con-
7 sidered a controlled substance in schedule A under
8 this subsection, except as provided in subparagraph
9 (B).

10 “(B) If the Secretary has determined, based on
11 relevant scientific studies and necessary data re-
12 quested by the Secretary and gathered by the Attor-
13 ney General, that a drug or other substance that has
14 been temporarily placed in schedule A does not have
15 sufficient potential for abuse to warrant control in
16 any schedule, and so advises the Attorney General in
17 writing, the Attorney General may not issue a per-
18 manent scheduling order under subparagraph (A)
19 and shall, within 30 days of receiving the Secretary’s
20 advice issue an order immediately terminating the
21 temporary scheduling order.

22 “(6) Before initiating proceedings under para-
23 graph (1), the Attorney General shall transmit no-
24 tice of a temporary order proposed to be issued to
25 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
10 take effect according to paragraph (2), except that
11 the temporary scheduling order may be disapproved
12 by an Act of Congress within 180 days from the
13 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)),
20 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

1 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
5 individual, or both. If any person commits such a violation
6 after a prior conviction for a felony drug offense has be-
7 come final, such person shall be sentenced to a term of
8 imprisonment of not more than 30 years and if death or
9 serious bodily injury results from the use of such sub-
10 stance shall be sentenced to not more than life imprison-
11 ment, a fine not to exceed the greater of twice that author-
12 ized in accordance with the provisions of title 18, United
13 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
16 States Code, any sentence imposing a term of imprison-
17 ment under this paragraph shall, in the absence of such
18 a prior conviction, impose a term of supervised release of
19 not less than 3 years in addition to such term of imprison-
20 ment and shall, if there was such a prior conviction, im-
21 pose a term of supervised release of not less than 6 years
22 in addition to such term of imprisonment. Notwith-
23 standing the prior sentence, and notwithstanding any
24 other provision of law, the court shall not place on proba-
25 tion 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.—

11 “(1) It shall be unlawful to import, export,
12 manufacture, distribute, dispense, or possess with
13 intent to manufacture, distribute, or dispense, a
14 schedule A substance or product containing a sched-
15 ule A substance, unless the substance or product
16 bears a label clearly identifying a schedule A sub-
17 stance or product containing a schedule A substance
18 by the nomenclature used by the International
19 Union of Pure and Applied Chemistry (IUPAC).

20 “(2)(A) A product described in subparagraph
21 (B) is exempt from the International Union of Pure
22 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

3 “(B) unless the Attorney General determines
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—

8 “(A) maintenance of effective control against
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

20 “(E) such other factors as may be relevant to
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),
24 the applicant shall not be required to apply for a separate
25 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

22 “(ii) request supplemental information from the
23 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-
25 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
23 registration is consistent with the public interest and
24 with the United States obligations under inter-

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-
 4 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).

7 “(3) If an applicant is registered to import or export
 8 a controlled substance in schedule I or II under subsection
 9 (a), the applicant shall not be required to apply for a sepa-
 10 rate registration under this subsection.”.

11 **SEC. 7. ADDITIONAL CONFORMING AMENDMENTS.**

12 (a) CONTROLLED SUBSTANCES ACT.—The Con-
 13 trolled Substances Act (21 U.S.C. 801 et seq.) is amend-
 14 ed—

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

16 (A) by striking “subsections (a) and (b)”
 17 and inserting “subsection (a), (b), (k), or (l)”;
 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,
 23 by striking “schedules I and II” and inserting
 24 “schedules I, II, and A”;

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

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 seq.) 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
10 “schedule I, II, or A”; and

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
21 striking “schedule I” and inserting “schedule I or
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

1 (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—

7 (1) in paragraph (6), by striking “or V” and in-
8 serting “V, or A”;

9 (2) in paragraph (14)—

10 (A) by striking “schedule I(c) and” and in-
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:

17 “(32)(A) Except as provided in subparagraph (C),
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-

1 tral nervous system of a controlled substance in
2 schedule I or II; or

3 “(ii) with respect to a particular person, which
4 such person represents or intends to have a stimu-
5 lant, depressant, or hallucinogenic effect on the cen-
6 tral nervous system that is substantially similar to
7 or greater than the stimulant, depressant, or hallu-
8 cinogenic effect on the central nervous system of a
9 controlled substance in schedule I or II.”.

10 **SEC. 9. RULES OF CONSTRUCTION.**

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

13 (1) the prosecution of offenses involving con-
14 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
17 temporarily or permanently schedule, reschedule, or
18 decontrol controlled substances under provisions of
19 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.**

23 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-

tees 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.

SEC. 11. REPORT ON CONTROLLED SUBSTANCE ANALOGUES SOLD BY MEANS OF THE INTERNET.

Not later than 1 year after the date of the enactment of this Act, and annually thereafter, the Administrator of the Drug Enforcement Administration shall make publicly available on the website of the Drug Enforcement Administration a report on, for the previous year, the lawful and unlawful sale of controlled substance analogues (as defined in section 102 of the Controlled Substances Act (21 U.S.C. 802)) by means of the Internet, including the following 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
16 U.S.C. 813) is amended—

17 (1) by striking “A controlled” and inserting
18 “(a) IN GENERAL.—A controlled”; and

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
25 of the substance.

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

4 “(3) The difference between the price at which
5 the substance is sold and the price at which the sub-
6 stance it is purported to be or advertised as is nor-
7 mally 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.

11 “(5) Whether the defendant knew or should
12 have known the substance was intended to be con-
13 sumed by injection, inhalation, ingestion, or any
14 other immediate means.

15 “(6) Any controlled substance analogue that is
16 manufactured, formulated, sold, distributed, or mar-
17 keted with the intent to avoid the provisions of exist-
18 ing drug laws.

19 “(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-

- 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
2^D 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.