

115TH CONGRESS
1ST SESSION**S.** _____

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

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

A BILL

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,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Stop the Importation
5 and Trafficking of Synthetic Analogues Act of 2017” or
6 the “SITSA Act”.

7 **SEC. 2. ESTABLISHMENT OF SCHEDULE A.**

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

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

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

8 “(6) SCHEDULE A.—

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

10 “(i) has—

11 “(I) a chemical structure that is sub-
12 stantially similar to the chemical structure
13 of a controlled substance in schedule I, II,
14 III, IV, or V; and

15 “(II) an actual or predicted stimulant,
16 depressant, or hallucinogenic effect on the
17 central nervous system that is substantially
18 similar to or greater than the stimulant,
19 depressant, or hallucinogenic effect on the
20 central nervous system of a controlled sub-
21 stance in schedule I, II, III, IV, or V; and

22 “(ii) is not—

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

1 “(II) with respect to a particular per-
2 son, subject to an exemption that is in ef-
3 fect for investigational use, for that person,
4 under section 505 of the Federal Food,
5 Drug, and Cosmetic Act (21 U.S.C. 355)
6 to the extent conduct with respect to such
7 substance is pursuant to such exemption.

8 “(B) PREDICTED STIMULANT, DEPRESSANT, OR
9 HALLUCINOGENIC EFFECT.—For purpose of this
10 paragraph, a predicted stimulant, depressant, or hal-
11 lucinogenic effect on the central nervous system may
12 be based on—

13 “(i) the chemical structure, structure activ-
14 ity relationships, binding receptor assays, or
15 other relevant scientific information about the
16 substance;

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

19 “(II) the clandestine importation, manu-
20 facture, or distribution, or diversion from legiti-
21 mate channels, of the substance; or

22 “(iii) the capacity of the substance to
23 cause a state of dependence, including physical
24 or psychological dependence that is similar to or

1 greater than that of a controlled substance in
2 schedule I, II, III, IV, or V.”; and

3 (3) in subsection (c)—

4 (A) in the matter preceding schedule I, by
5 striking “IV, and V” and inserting “IV, V, and
6 A”; and

7 (B) by adding at the end the following:

8 “SCHEDULE A

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

12 “(1) 4-fluoroisobutyryl fentanyl.

13 “(2) Valeryl fentanyl.

14 “(3) 4-methoxybutyryl fentanyl.

15 “(4) 4-methylphenethyl acetyl fentanyl.

16 “(5) 3-furanyl fentanyl.

17 “(6) Ortho-fluorofentanyl.

18 “(7) Tetrahydrofuranyl fentanyl.

19 “(8) Ocfentanil.

20 “(9) 4-fluorobutyryl fentanyl.

21 “(10) Methoxyacetyl fentanyl.

22 “(11) Meta-fluorofentanyl.

23 “(12) Isobutyryl fentanyl.

24 “(13) Acryl fentanyl.”.

1 **SEC. 3. TEMPORARY AND PERMANENT SCHEDULING OF**
2 **SCHEDULE A SUBSTANCES.**

3 Section 201 of the Controlled Substances Act (21
4 U.S.C. 811) is amended by adding at the end the fol-
5 lowing:

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

8 “(1) The Attorney General may issue a tem-
9 porary order adding a drug or substance to schedule
10 A if the Attorney General finds that—

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

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

17 “(2) A temporary scheduling order issued under
18 paragraph (1) shall not take effect until 30 days
19 after the date of the publication by the Attorney
20 General of a notice in the Federal Register of the in-
21 tention to issue such order and the grounds upon
22 which such order is to be issued. The temporary
23 scheduling order shall expire not later than 5 years
24 after the date it becomes effective, except that the
25 Attorney General may, during the pendency of pro-

1 ceedings under paragraph (5), extend the temporary
2 scheduling order for up to 180 days.

3 “(3) A temporary scheduling order issued under
4 paragraph (1) shall be vacated upon the issuance of
5 a permanent order issued under paragraph (5) with
6 regard to the same substance, or upon the subse-
7 quent issuance of any scheduling order under this
8 section.

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

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

19 “(6) Before initiating proceedings under para-
20 graph (1) or (5), the Attorney General shall trans-
21 mit notice of an order proposed to be issued to the
22 Secretary of Health and Human Services. In issuing
23 an order under paragraph (1) or (5), the Attorney
24 General shall take into consideration any comments
25 submitted by the Secretary of Health and Human

1 Services in response to a notice transmitted pursu-
2 ant to this paragraph.”.

3 **SEC. 4. PENALTIES.**

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

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

9 “(F)(i) In the case of any controlled substance in
10 schedule A, such person shall be sentenced to a term of
11 imprisonment of not more than 10 years and if death or
12 serious bodily injury results from the use of such sub-
13 stance shall be sentenced to a term of imprisonment of
14 not more than 15 years, a fine not to exceed the greater
15 of that authorized in accordance with the provisions of
16 title 18, United States Code, or \$500,000 if the defendant
17 is an individual or \$2,500,000 if the defendant is other
18 than an individual, or both.

19 “(ii) If any person commits such a violation after a
20 prior conviction for a felony drug offense has become final,
21 such person shall be sentenced to a term of imprisonment
22 of not more than 20 years and if death or serious bodily
23 injury results from the use of such substance shall be sen-
24 tenced to a term of imprisonment of not more than 30
25 years, a fine not to exceed the greater of twice that author-

1 ized in accordance with the provisions of title 18, United
2 States Code, or \$1,000,000 if the defendant is an indi-
3 vidual or \$5,000,000 if the defendant is other than an in-
4 dividual, or both.

5 “(iii) Any sentence imposing a term of imprisonment
6 under this subparagraph shall, in the absence of such a
7 prior conviction, impose a term of supervised release of
8 not less than 2 years in addition to such term of imprison-
9 ment and shall, if there was such a prior conviction, im-
10 pose a term of supervised release of not less than 4 years
11 in addition to such term of imprisonment.”;

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

13 (A) in paragraph (8), by striking “or” at
14 the end;

15 (B) in paragraph (9), by striking the pe-
16 riod at the end and inserting “; or”; and

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

19 “(10) to export a substance in violation of the
20 controlled substance laws of the country to which
21 the substance is exported.”; and

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

24 “(b) A person shall not be subject to a criminal or
25 civil penalty under this title or under any other Federal

1 law solely for possession of a schedule A controlled sub-
2 stance.”.

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

7 “(8) In the case of a violation under subsection (a)
8 involving a controlled substance in schedule A, the person
9 committing such violation shall be sentenced to a term of
10 imprisonment of not more than 20 years and if death or
11 serious bodily injury results from the use of such sub-
12 stance shall be sentenced to a term of imprisonment for
13 any term of years or for life, a fine not to exceed the great-
14 er of that authorized in accordance with the provisions of
15 title 18, United States Code, or \$1,000,000 if the defend-
16 ant is an individual or \$5,000,000 if the defendant is other
17 than an individual, or both. If any person commits such
18 a violation after a prior conviction for a felony drug of-
19 fense has become final, such person shall be sentenced to
20 a term of imprisonment of not more than 30 years and
21 if death or serious bodily injury results from the use of
22 such substance shall be sentenced to a term of imprison-
23 ment for any term of years or for life, a fine not to exceed
24 the greater of twice that authorized in accordance with
25 the provisions of title 18, United States Code, or

1 \$2,000,000 if the defendant is an individual or
2 \$10,000,000 if the defendant is other than an individual,
3 or both. Notwithstanding section 3583 of title 18, United
4 States Code, any sentence imposing a term of imprison-
5 ment under this paragraph shall, in the absence of such
6 a prior conviction, impose a term of supervised release of
7 not less than 3 years in addition to such term of imprison-
8 ment and shall, if there was such a prior conviction, im-
9 pose a term of supervised release of not less than 6 years
10 in addition to such term of imprisonment. Notwith-
11 standing the prior sentence, and notwithstanding any
12 other provision of law, the court shall not place on proba-
13 tion or suspend the sentence of any person sentenced
14 under the provisions of this paragraph which provide for
15 a mandatory term of imprisonment if death or serious
16 bodily injury results.”.

17 **SEC. 5. FALSE LABELING OF SCHEDULE A CONTROLLED**
18 **SUBSTANCES.**

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

22 “(f) FALSE LABELING OF SCHEDULE A CON-
23 TROLLED SUBSTANCES.—

24 “(1) It shall be unlawful to import, export,
25 manufacture, distribute, dispense, or possess with

1 intent to manufacture, distribute, or dispense, a
2 schedule A substance or product containing a sched-
3 ule A substance, unless the substance or product
4 bears a label clearly identifying a schedule A sub-
5 stance or product containing a schedule A substance
6 by the nomenclature used by the International
7 Union of Pure and Applied Chemistry (IUPAC).

8 “(2)(A) A product described in subparagraph
9 (B) is exempt from the International Union of Pure
10 and Applied Chemistry nomenclature requirement of
11 this subsection if such product is labeled in the man-
12 ner required under the Federal Food, Drug, and
13 Cosmetic Act.

14 “(B) A product is described in this subpara-
15 graph if the product—

16 “(i) is the subject of an approved applica-
17 tion as described in section 505(b) or (j) of the
18 Federal Food, Drug, and Cosmetic Act; or

19 “(ii) is exempt from the provisions of sec-
20 tion 505 of such Act relating to new drugs be-
21 cause—

22 “(I) it is intended solely for investiga-
23 tional use as described in section 505(i) of
24 such Act; and

1 “(II) such product is being used ex-
2 clusively for purposes of a clinical trial
3 that is the subject of an effective investiga-
4 tional new drug application.”.

5 (b) PENALTIES.—Section 402 of the Controlled Sub-
6 stances Act (21 U.S.C. 842) is amended—

7 (1) in subsection (a)(16), by inserting “or sub-
8 section (f)” after “subsection (e)”; and

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

11 **SEC. 6. REGISTRATION REQUIREMENTS FOR HANDLERS OF**
12 **SCHEDULE A SUBSTANCES.**

13 (a) CONTROLLED SUBSTANCES ACT.—Section 303 of
14 the Controlled Substances Act (21 U.S.C. 823) is amend-
15 ed—

16 (1) in subsection (f), in the undesignated mat-
17 ter following paragraph (5)—

18 (A) by inserting “or A” after “schedule I”
19 each place it appears; and

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

1 retary shall determine the merits of the re-
2 search protocol submitted by the practitioner
3 registering to engage in research with a con-
4 trolled substance in schedule A, and the Attor-
5 ney General may deny or revoke the registra-
6 tion only on a ground specified in section 304.”;
7 and

8 (2) by adding at the end the following:

9 “(k)(1) The Attorney General shall register an appli-
10 cant to manufacture schedule A substances if—

11 “(A) the applicant demonstrates that the sched-
12 ule A substances will be used for research, analyt-
13 ical, or industrial purposes approved by the Attorney
14 General; and

15 “(B) the Attorney General determines that such
16 registration is consistent with the public interest and
17 with the United States obligations under inter-
18 national treaties, conventions, or protocols in effect
19 on the date of enactment of this subsection.

20 “(2) In determining the public interest under para-
21 graph (1)(B), the Attorney General shall consider—

22 “(A) maintenance of effective controls against
23 diversion of particular controlled substances and any
24 controlled substance in schedule A compounded
25 therefrom into other than legitimate medical, sci-

1 entific, research, or industrial channels, by limiting
2 the importation and bulk manufacture of such con-
3 trolled substances to a number of establishments
4 which can produce an adequate and uninterrupted
5 supply of these substances under adequately com-
6 petitive conditions for legitimate medical, scientific,
7 research, and industrial purposes;

8 “(B) compliance with applicable State and local
9 law;

10 “(C) promotion of technical advances in the art
11 of manufacturing substances described in subpara-
12 graph (A) and the development of new substances;

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

17 “(E) past experience in the manufacture of con-
18 trolled substances, and the existence in the establish-
19 ment of effective control against diversion; and

20 “(F) 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 manufacture con-
23 trolled substances in schedule I or II under subsection (a),
24 the applicant shall not be required to apply for a separate
25 registration under this subsection.

1 “(1)(1) The Attorney General shall register an appli-
2 cant to distribute schedule A substances—

3 “(A) if the applicant demonstrates that the
4 schedule A substances will be used for research, ana-
5 lytical, or industrial purposes approved by the Attor-
6 ney General; and

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

10 “(2) In determining the public interest under para-
11 graph (1)(B), the Attorney General shall consider—

12 “(A) maintenance of effective control against
13 diversion of particular controlled substances into
14 other than legitimate medical, scientific, and indus-
15 trial channels;

16 “(B) compliance with applicable State and local
17 law;

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

22 “(D) past experience in the distribution of con-
23 trolled substances; and

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

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

5 “(m)(1) Not later than 90 days after the date on
6 which a substance is placed in schedule A, any practitioner
7 who was engaged in research on the substance before the
8 placement of the substance in schedule A and any manu-
9 facturer or distributor who was handling the substance be-
10 fore the placement of the substance in schedule A shall
11 register with the Attorney General.

12 “(2)(A) Not later than 60 days after the date on
13 which the Attorney General receives an application for
14 registration to conduct research on a schedule A sub-
15 stance, the Attorney General shall—

16 “(i) grant, or initiate proceedings under section
17 304(e) to deny, the application; or

18 “(ii) request supplemental information from the
19 applicant.

20 “(B) Not later than 30 days after the date on which
21 the Attorney General receives supplemental information
22 requested under subparagraph (A)(ii) in connection with
23 an application described in subparagraph (A), the Attor-
24 ney General shall grant or deny the application.”.

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

5 “(j)(1) The Attorney General shall register an appli-
6 cant to import or export a schedule A substance if—

7 “(A) the applicant demonstrates that the sched-
8 ule A substances will be used for research, analyt-
9 ical, or industrial purposes approved by the Attorney
10 General; and

11 “(B) the Attorney General determines that such
12 registration is consistent with the public interest and
13 with the United States obligations under inter-
14 national treaties, conventions, or protocols in effect
15 on the date of enactment of this subsection.

16 “(2) In determining the public interest under para-
17 graph (1)(B), the Attorney General shall consider the fac-
18 tors described in subparagraphs (A) through (F) of sec-
19 tion 303(k)(2).

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

1 **SEC. 7. ADDITIONAL CONFORMING AMENDMENTS.**

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

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

6 (A) by striking “subsections (a) and (b)”
7 and inserting “subsection (a), (b), (k), or (l)”;
8 and

9 (B) by striking “schedule I or II” and in-
10 serting “schedule I, II, or A”;

11 (2) in section 306 (21 U.S.C. 826)—

12 (A) in subsection (a), in the first sentence,
13 by striking “schedules I and II” and inserting
14 “schedules I, II, and A”;

15 (B) in subsection (b), in the second sen-
16 tence, by striking “schedule I or II” and insert-
17 ing “schedule I, II, or A”;

18 (C) in subsection (c), in the first sentence,
19 by striking “schedules I and II” and inserting
20 “schedules I, II, and A”;

21 (D) in subsection (d), in the first sentence,
22 by striking “schedule I or II” and inserting
23 “schedule I, II, or A”;

24 (E) in subsection (e), in the first sentence,
25 by striking “schedule I or II” and inserting
26 “schedule I, II, or A”; and

1 (F) in subsection (f), in the first sentence,
2 by striking “schedules I and II” and inserting
3 “schedules I, II, and A”;

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

7 (4) in section 402(b) (21 U.S.C. 842(b)), in the
8 matter preceding paragraph (1), by striking “sched-
9 ule I or II” and inserting “schedule I, II, or A”;

10 (5) in section 403(a)(1) (21 U.S.C. 843(a)(1)),
11 by striking “schedule I or II” and inserting “sched-
12 ule I, II, or A”; and

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

16 (b) CONTROLLED SUBSTANCES IMPORT EXPORT
17 ACT.—The Controlled Substances Import and Export Act
18 (21 U.S.C. 951 et seq.) is amended—

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

20 (A) in the matter preceding paragraph (1),
21 by striking “schedule I or II” and inserting
22 “schedule I, II, or A”; and

23 (B) in paragraph (2), by striking “sched-
24 ule I or II” and inserting “schedule I, II, or
25 A”;

1 (2) in section 1003 (21 U.S.C. 953)—

2 (A) in subsection (c), in the matter pre-
3 ceeding paragraph (1), by striking “schedule I or
4 II” and inserting “schedule I, II, or A”; and

5 (B) in subsection (d), by striking “schedule
6 I or II” and inserting “schedule I, II, or A”;

7 (3) in section 1004(1) (21 U.S.C. 954(1)), by
8 striking “schedule I” and inserting “schedule I or
9 A”;

10 (4) in section 1005 (21 U.S.C. 955), by striking
11 “schedule I or II” and inserting “schedule I, II, or
12 A”; and

13 (5) in section 1009(a) (21 U.S.C. 959(a)), by
14 striking “schedule I or II” and inserting “schedule
15 I, II, or A”.

16 **SEC. 8. CLARIFICATION OF THE DEFINITION OF CON-**
17 **TROLLED SUBSTANCE ANALOGUE UNDER**
18 **THE ANALOGUE ENFORCEMENT ACT.**

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

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

23 (2) in paragraph (14)—

24 (A) by striking “schedule I(c) and” and in-
25 serting “schedule I(c), schedule A, and”; and

1 (B) by striking “schedule I(e),” and insert-
2 ing “schedule I(e) and schedule A,”; and
3 (3) in paragraph (32)(A), by striking “(32)(A)”
4 and all that follows through clause (iii) and inserting
5 the following:

6 “(32)(A) Except as provided in subparagraph (C),
7 the term ‘controlled substance analogue’ means a sub-
8 stance whose chemical structure is substantially similar to
9 the chemical structure of a controlled substance in sched-
10 ule I or II—

11 “(i) which has a stimulant, depressant, or hallueino-
12 genic effect on the central nervous system that is substan-
13 tially similar to or greater than the stimulant, depressant,
14 or hallucinogenic effect on the central nervous system of
15 a controlled substance in schedule I or II; or

16 “(ii) with respect to a particular person, which such
17 person represents or intends to have a stimulant, depres-
18 sant, or hallucinogenic effect on the central nervous sys-
19 tem that is substantially similar to or greater than the
20 stimulant, depressant, or hallucinogenic effect on the cen-
21 tral nervous system of a controlled substance in schedule
22 I or II.”.

23 **SEC. 9. RULES OF CONSTRUCTION.**

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

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

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