

116TH CONGRESS
1ST SESSION

H. R. 4963

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

IN THE HOUSE OF REPRESENTATIVES

OCTOBER 31, 2019

Mr. KATKO (for himself, Miss RICE of New York, Mr. WALDEN, Mr. CORREA, and Mr. SOTO) introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committee on the Judiciary, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

A BILL

To amend the Controlled Substances Act to clarify how controlled substance analogues that are imported or offered for import 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; TABLE OF CONTENTS.**

4 (a) SHORT TITLE.—This Act may be cited as the
5 “Stop the Importation and Manufacturing of Synthetic
6 Analogues Act of 2019” or “SIMSA”.

1 (b) TABLE OF CONTENTS.—The table of contents of
 2 this Act is as follows:

- Sec. 1. Short title; table of contents.
- Sec. 2. Establishment of schedule A.
- Sec. 3. Temporary and permanent scheduling of schedule A substances.
- Sec. 4. Penalties.
- Sec. 5. False labeling of schedule A controlled substances.
- Sec. 6. Registration requirements for importers and exporters of schedule A substances.
- Sec. 7. Additional conforming amendments.
- Sec. 8. Sentencing review.
- Sec. 9. Rules of construction.

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

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

6 (1) in subsection (a), by striking “five schedules
 7 of controlled substances, to be known as schedules I,
 8 II, III, IV, and V” and inserting “six schedules of
 9 controlled substances, to be known as schedules I,
 10 II, III, IV, V, and A”;

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

13 “(6) SCHEDULE A.—

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

15 “(i) is or has been imported, or is offered
 16 for import, into the United States;

17 “(ii) has—

18 “(I) a chemical structure that is sub-
 19 stantially similar to the chemical structure

1 of a controlled substance in schedule I, II,
2 III, IV, or V; and

3 “(II) an actual or predicted stimulant,
4 depressant, or hallucinogenic effect on the
5 central nervous system that is substantially
6 similar to or greater than the stimulant,
7 depressant, or hallucinogenic effect on the
8 central nervous system of a controlled sub-
9 stance in schedule I, II, III, IV, or V; and
10 “(iii) is not—

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

14 “(II) with respect to a particular per-
15 son, subject to an exemption that is in ef-
16 fect for investigational use, for that person,
17 under section 505 of the Federal Food,
18 Drug, and Cosmetic Act (21 U.S.C. 355)
19 to the extent conduct with respect to such
20 substance is pursuant to such exemption.

21 “(B) PREDICTED STIMULANT, DEPRESSANT, OR
22 HALLUCINOGENIC EFFECT.—For purposes of this
23 paragraph, a predicted stimulant, depressant, or hal-
24 lucinogenic effect on the central nervous system may
25 be based on—

1 “(i)(I) the chemical structure; and

2 “(II)(aa) the structure activity relation-
3 ships; or

4 “(bb) binding receptor assays and other
5 relevant scientific information about the sub-
6 stance;

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

9 “(II) the clandestine importation, manu-
10 facture, or distribution, or diversion from legiti-
11 mate channels, of the substance; or

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

17 (3) in subsection (c)—

18 (A) in the matter preceding schedule I, by
19 striking “IV, and V” and inserting “IV, V, and
20 A”; and

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

22 “SCHEDULE A

23 “Any substance temporarily or permanently sched-
24 uled by the Attorney General in accordance with section
25 201(k).”.

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) IN GENERAL.—The Attorney General may
9 issue a temporary order adding a drug or substance
10 to schedule 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 of the
16 drug or other substance.

17 “(2) DURATION OF TEMPORARY SCHEDULING
18 ORDER.—A temporary scheduling order issued under
19 paragraph (1) shall—

20 “(A) not take effect until 30 days after the
21 date of the publication by the Attorney General
22 of a notice in the Federal Register of the inten-
23 tion to issue such order and the grounds upon
24 which such order is to be issued; and

25 “(B) expire not later than 5 years after
26 the date on which the order becomes effective,

1 except that the Attorney General may, during
2 the pendency of proceedings under paragraph
3 (5), extend the temporary scheduling order for
4 up to 180 days.

5 “(3) EFFECT OF ISSUANCE OF PERMANENT
6 SCHEDULING ORDER.—A temporary scheduling
7 order issued under paragraph (1) shall be vacated
8 upon the issuance of a permanent order issued
9 under paragraph (5) with regard to the same sub-
10 stance, or upon the subsequent issuance of any
11 scheduling order under this section.

12 “(4) LIMITATION ON JUDICIAL REVIEW.—A
13 temporary scheduling order issued under paragraph
14 (1) shall not be subject to judicial review.

15 “(5) PERMANENT SCHEDULING ORDER.—

16 “(A) IN GENERAL.—Except as provided in
17 subparagraph (B), not earlier than 3 years
18 after the date on which the Attorney General
19 issues an order temporarily scheduling a drug
20 or substance under this subsection, the Attor-
21 ney General may, by rule, issue a permanent
22 order adding the drug or other substance to
23 schedule A if such drug or substance satisfies
24 the criteria for being considered a schedule A
25 substance.

1 “(B) LIMITATION.—If the Secretary of
2 Health and Human Services has determined,
3 based on relevant scientific studies and nec-
4 essary data requested by the Secretary of
5 Health and Human Services and gathered by
6 the Attorney General, that a drug or other sub-
7 stance that has been temporarily placed in
8 schedule A does not have sufficient potential for
9 abuse to warrant control in any schedule, and
10 provides written notice of such determination to
11 the Attorney General, the Attorney General—

12 “(i) may not issue a permanent sched-
13 uling order under subparagraph (A); and

14 “(ii) not later than 30 days after the
15 date on which the Attorney General re-
16 ceives such notice, shall issue an order im-
17 mediately terminating the temporary
18 scheduling order for the drug or other sub-
19 stance.

20 “(6) NOTICE TO HHS.—Before initiating pro-
21 ceedings under paragraph (1), the Attorney General
22 shall transmit notice of a temporary order proposed
23 to be issued to the Secretary of Health and Human
24 Services. In issuing an order under paragraph (1),
25 the Attorney General shall take into consideration

1 any comments submitted by the Secretary of Health
2 and Human Services in response to a notice trans-
3 mitted pursuant to this paragraph.”.

4 **SEC. 4. PENALTIES.**

5 Section 1010 of the Controlled Substances Import
6 and Export Act (21 U.S.C. 960) is amended—

7 (1) in subsection (a), by inserting “or a drug or
8 substance in schedule A” after “controlled sub-
9 stance” each place it appears; and

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

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

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

1 **SEC. 5. FALSE LABELING OF SCHEDULE A CONTROLLED**
2 **SUBSTANCES.**

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

6 “(f) FALSE LABELING OF SCHEDULE A CON-
7 TROLLED SUBSTANCES.—

8 “(1) It shall be unlawful to import or export,
9 with intent to manufacture, distribute, or dispense,
10 a schedule A substance or product containing a
11 schedule A substance, unless the substance or prod-
12 uct bears a label clearly identifying a schedule A
13 substance or product containing a schedule A sub-
14 stance by the nomenclature used by the Inter-
15 national Union of Pure and Applied Chemistry
16 (IUPAC).

17 “(2)(A) A product described in subparagraph
18 (B) is exempt from the International Union of Pure
19 and Applied Chemistry nomenclature requirement of
20 this subsection if such product is labeled in the man-
21 ner required under the Federal Food, Drug, and
22 Cosmetic Act.

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

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

4 “(ii) is exempt from the provisions of sec-
5 tion 505 of such Act relating to new drugs be-
6 cause—

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

10 “(II) such product is being used ex-
11 clusively for purposes of a clinical trial
12 that is the subject of an effective investiga-
13 tional new drug application.”.

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

16 (1) in subsection (a)—

17 (A) in paragraph (16), by striking “or” at
18 the end;

19 (B) by redesignating paragraph (17) as
20 paragraph (18); and

21 (C) by inserting after paragraph (16) the
22 following:

23 “(17) to violate section 305(f); or”; and

24 (2) in subsection (c)—

25 (A) in paragraph (1)—

- 1 (i) in subparagraph (B)(i), by striking
 2 “(17)” and inserting “(18)”; and
 3 (ii) in subparagraph (C), by inserting
 4 “or (17)” after “paragraph (16)” each
 5 place it appears; and
 6 (B) in paragraph (2)(D), by striking
 7 “(17)” and inserting “(18)”.

8 **SEC. 6. REGISTRATION REQUIREMENTS FOR IMPORTERS**
 9 **AND EXPORTERS OF SCHEDULE A SUB-**
 10 **STANCES.**

11 Section 1008 of the Controlled Substances Import
 12 and Export Act (21 U.S.C. 958) is amended by adding
 13 at the end the following:

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

16 “(A) the applicant demonstrates that the sched-
 17 ule A substance will be used for research, analytical,
 18 or industrial purposes approved by the Attorney
 19 General; and

20 “(B) the Attorney General determines that such
 21 registration is consistent with the public interest and
 22 with the United States obligations under inter-
 23 national treaties, conventions, or protocols in effect
 24 on the date of enactment of this subsection.

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

3 “(A) maintenance of effective controls against
4 diversion of particular controlled substances and any
5 controlled substance in schedule A compounded
6 therefrom into other than legitimate medical, sci-
7 entific, research, or industrial channels, by limiting
8 the importation and bulk manufacture of such con-
9 trolled substances to a number of establishments
10 which can produce an adequate and uninterrupted
11 supply of these substances under adequately com-
12 petitive conditions for legitimate medical, scientific,
13 research, and industrial purposes;

14 “(B) compliance with applicable State and local
15 law;

16 “(C) promotion of technical advances in the art
17 of manufacturing substances described in subpara-
18 graph (A) and the development of new substances;

19 “(D) prior conviction record of applicant under
20 Federal and State laws relating to the importation,
21 manufacture, distribution, or dispensing of sub-
22 stances described in subparagraph (A);

23 “(E) past experience in the importation and
24 manufacture of controlled substances, and the exist-

1 ence in the establishment of effective control against
2 diversion; and

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

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

9 **SEC. 7. ADDITIONAL CONFORMING AMENDMENTS.**

10 The Controlled Substances Import and Export Act
11 (21 U.S.C. 951 et seq.) is amended—

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

13 (A) in the matter preceding paragraph (1),
14 by inserting “or drug or substance in schedule
15 A” after “schedule I or II”; and

16 (B) in paragraph (2), by inserting “or
17 drug or substances in schedule A” after “sched-
18 ule I or II”;

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

20 (A) in subsection (c), in the matter pre-
21 ceding paragraph (1), by inserting “or drug or
22 substance in schedule A” after “schedule I or
23 II”; and

1 (B) in subsection (d), by inserting “or
2 drug or substance in schedule A” after “sched-
3 ule I or II”;

4 (3) in section 1004(1) (21 U.S.C. 954(1)), in
5 the matter preceding subparagraph (A), by inserting
6 “or drug or substance in schedule A” after “sched-
7 ule I”;

8 (4) in section 1005 (21 U.S.C. 955), by insert-
9 ing “or drug or substance in schedule A” after
10 “schedule I or II”; and

11 (5) in section 1009(a) (21 U.S.C. 959(a)), by
12 inserting “or drug or substance in schedule A” after
13 “schedule I or II”.

14 **SEC. 8. SENTENCING REVIEW.**

15 (a) COVERED OFFENSE DEFINED.—In this section,
16 the term “covered offense” means an offense involving a
17 schedule A substance for which the penalty was estab-
18 lished under section 4 or 5 of this Act.

19 (b) SENTENCING REVIEW.—

20 (1) PETITION FOR REVIEW.—If a schedule A
21 substance that is temporarily or permanently sched-
22 uled under section 201(k) of the Controlled Sub-
23 stances Act, as added by this Act, is subsequently
24 descheduled or rescheduled on a schedule with lower
25 penalties, any individual convicted of a covered of-

1 fense involving such schedule A substance who is
2 awaiting sentencing or is still serving a term of im-
3 prisonment for such covered offense on the date of
4 the descheduling or rescheduling may petition the
5 court that imposed the sentence for a sentencing re-
6 duction hearing for such covered offense.

7 (2) SENTENCING REVIEW.—Not later than 30
8 days after the date on which a petition is filed under
9 paragraph (1), the court shall conduct a sentencing
10 reduction hearing and may modify the sentence of
11 the petitioner as if the descheduling or rescheduling
12 described in paragraph (1) had been in effect on the
13 date the covered offense was committed.

14 **SEC. 9. RULES OF CONSTRUCTION.**

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

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

20 (2) the authority of the Attorney General to
21 temporarily or permanently schedule, reschedule, or
22 decontrol controlled substances under provisions of
23 section 201 of the Controlled Substances Act (21

1 U.S.C. 811) that are in effect on the day before the
2 date of enactment of this Act.

○