

117TH CONGRESS
1ST SESSION

H. R. 4459

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

JULY 16, 2021

Mr. KATKO (for himself and Miss RICE of New York) 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 2021” or “SIMSA”.

7 (b) **TABLE OF CONTENTS.**—The table of contents of
8 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 schedule A substances.
 Sec. 7. Additional conforming amendments.
 Sec. 8. Sentencing review.
 Sec. 9. Rules of construction.

1 SEC. 2. ESTABLISHMENT OF SCHEDULE A.

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

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

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

11 “(6) SCHEDULE A.—

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

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

15 “(ii) has—

16 “(I) a chemical structure that is sub-
 17 stantially similar to the chemical structure
 18 of a controlled substance in schedule I, II,
 19 III, IV, or V; and

20 “(II) an actual or predicted stimulant,
 21 depressant, or hallucinogenic effect on the

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

7 “(I) listed or otherwise included in
8 any other schedule in this section or by
9 regulation of the Attorney General; and

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

17 “(B) PREDICTED STIMULANT, DEPRESSANT, OR
18 HALLUCINOGENIC EFFECT.—For purpose of this
19 paragraph, a predicted stimulant, depressant, or hal-
20 lucinogenic effect on the central nervous system may
21 be based on—

22 “(i)(I) the chemical structure; and

23 “(II)(aa) the structure activity relation-
24 ships; or

1 “(bb) binding receptor assays and other
2 relevant scientific information about the sub-
3 stance;

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

6 “(II) the clandestine importation, manu-
7 facture, or distribution, or diversion from legiti-
8 mate channels, of the substance; or

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

14 (3) in subsection (c)—

15 (A) in the matter preceding schedule I, by
16 striking “IV, and V” and inserting “IV, V, and
17 A”; and

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

19 “SCHEDULE A

20 “Any substance temporarily or permanently sched-
21 uled by the Attorney General in accordance with section
22 201(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 SCHEDULE A**
9 **SUBSTANCES.**

10 (a) REGISTRATION REQUIREMENTS FOR IMPORTERS
11 AND EXPORTERS OF SCHEDULE A SUBSTANCES.—Sec-
12 tion 1008 of the Controlled Substances Import and Export
13 Act (21 U.S.C. 958) is amended by adding at the end the
14 following:

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

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

21 “(B) the Attorney General determines that such
22 registration is consistent with the public interest and
23 with the United States obligations under inter-
24 national treaties, conventions, or protocols in effect
25 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 (b) CONTINUATION OF RESEARCH ON SUBSTANCES
10 NEWLY ADDED TO SCHEDULE A.—Section 302(e) of the
11 Controlled Substances Act (21 U.S.C. 822(e)) is amended
12 by adding at the end the following:

13 “(3)(A) If a person is conducting research on a sub-
14 stance at the time the substance is added to schedule A,
15 and such person is already registered to conduct research
16 with a controlled substance in schedule I or II, then—

17 “(i) the person shall, within 30 days of the
18 scheduling of the newly scheduled substance, submit
19 a completed application for registration or modifica-
20 tion of existing registration, to conduct research on
21 such substance, in accordance with the regulations
22 issued by the Attorney General;

23 “(ii) the person may continue to conduct the re-
24 search on such substance until the application de-
25 scribed in clause (i) is withdrawn by the applicant

1 or until the Attorney General serves on the applicant
2 an order to show cause proposing the denial of the
3 application pursuant to section 304(c); and

4 “(iii) if the Attorney General serves order to
5 show cause under clause (ii) and the applicant re-
6 quests a hearing, such hearing shall be held on an
7 expedited basis and not later than 45 days after the
8 request is made, except that the hearing may be held
9 at a later time if so requested by the applicant.

10 “(B) A person who is registered to conduct research
11 with a controlled substance in schedule A may conduct re-
12 search with another controlled substance in schedule I,
13 only if—

14 “(i) the person has applied for a modification of
15 the person’s registration to authorize research with
16 such other controlled substance in accordance with
17 the regulations issued by the Attorney General;

18 “(ii) the Attorney General has obtained
19 verification from the Secretary that the research
20 protocol submitted with the application is meri-
21 torious; and

22 “(iii) the Attorney General has determined, not
23 later than 30 days after receiving the application de-
24 scribed in clause (i), that such activity is consistent

1 with United States obligations under the Single Con-
2 vention on Narcotic Drugs, 1961.

3 “(C) Nothing in this paragraph shall be construed to
4 alter the authority of the Attorney General to initiate pro-
5 ceedings to deny, suspend, or revoke any registration in
6 accordance with sections 303 and 304.”.

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

8 The Controlled Substances Import and Export Act
9 (21 U.S.C. 951 et seq.) is amended—

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

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

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

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

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

22 (B) in subsection (d), by inserting “or
23 drug or substance in schedule A” after “sched-
24 ule I or II”;

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

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

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

11 **SEC. 8. SENTENCING REVIEW.**

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

16 (b) SENTENCING REVIEW.—

17 (1) PETITION FOR REVIEW.—If a schedule A
18 substance that is temporarily or permanently sched-
19 uled under section 201(k) of the Controlled Sub-
20 stances Act, as added by this Act, is subsequently
21 descheduled or rescheduled on a schedule with lower
22 penalties, any individual convicted of a covered of-
23 fense involving such schedule A substance who is
24 awaiting sentencing or is still serving a term of im-
25 prisonment for such covered offense on the date of

1 the descheduling or rescheduling may petition the
2 court that imposed the sentence for a sentencing re-
3 duction hearing for such covered offense.

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

11 **SEC. 9. RULES OF CONSTRUCTION.**

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

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

17 (2) the authority of the Attorney General to
18 temporarily or permanently schedule, reschedule, or
19 decontrol controlled substances under provisions of
20 section 201 of the Controlled Substances Act (21
21 U.S.C. 811) that are in effect on the day before the
22 date of enactment of this Act.

○