

119TH CONGRESS
1ST SESSION

S. 3228

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 SENATE OF THE UNITED STATES

NOVEMBER 20, 2025

Mr. GRASSLEY (for himself, Ms. HASSAN, Ms. ERNST, Mrs. SHAHEEN, and Mrs. CAPITO) introduced the following bill; which was read twice and referred to the Committee on the Judiciary

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 2025” or the “SIMSA Act of 2025”.

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 listed or otherwise included in
7 any other schedule in this section or by regula-
8 tion of the Attorney General.

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

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

15 “(II)(aa) the structure activity relation-
16 ships; or

17 “(bb) binding receptor assays and other
18 relevant scientific information about the sub-
19 stance;

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

22 “(II) the clandestine importation, manu-
23 facture, or distribution, or diversion from legiti-
24 mate channels, of the substance; or

1 “(iii) the capacity of the substance to
 2 cause a state of dependence, including physical
 3 or psychological dependence that is similar to or
 4 greater than that of a controlled substance in
 5 schedule I, II, III, IV, or V.”; and

6 (3) in subsection (c)—

7 (A) in the matter preceding schedule I, by
 8 striking “IV, and V” and inserting “IV, V, and
 9 A”; and

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

11 “SCHEDULE A

12 “Any substance temporarily or permanently sched-
 13 uled by the Attorney General in accordance with section
 14 201(k).”.

15 **SEC. 3. TEMPORARY AND PERMANENT SCHEDULING OF**
 16 **SCHEDULE A SUBSTANCES.**

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

20 “(k) TEMPORARY AND PERMANENT SCHEDULING OF
 21 SCHEDULE A SUBSTANCES.—

22 “(1) IN GENERAL.—The Attorney General may
 23 issue a temporary order adding a drug or substance
 24 to schedule 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) DURATION OF TEMPORARY SCHEDULING
8 ORDER.—A temporary scheduling order issued under
9 paragraph (1) shall—

10 “(A) not take effect until 30 days after the
11 date of the publication by the Attorney General
12 of a notice in the Federal Register of the inten-
13 tion to issue such order and the grounds upon
14 which such order is to be issued; and

15 “(B) expire not later than 5 years after
16 the date on which the order becomes effective,
17 except that the Attorney General may, during
18 the pendency of proceedings under paragraph
19 (5), extend the temporary scheduling order for
20 up to 180 days.

21 “(3) EFFECT OF ISSUANCE OF PERMANENT
22 SCHEDULING ORDER.—A temporary scheduling
23 order issued under paragraph (1) shall be vacated
24 upon the issuance of a permanent order issued
25 under paragraph (5) with regard to the same sub-

1 stance, or upon the subsequent issuance of any
2 scheduling order under this section.

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

6 “(5) PERMANENT SCHEDULING ORDER.—

7 “(A) IN GENERAL.—Except as provided in
8 subparagraph (B), not earlier than 3 years
9 after the date on which the Attorney General
10 issues an order temporarily scheduling a drug
11 or substance under this subsection, the Attor-
12 ney General may, by rule, issue a permanent
13 order adding the drug or other substance to
14 schedule A if such drug or substance satisfies
15 the criteria for being considered a schedule A
16 substance.

17 “(B) LIMITATION.—If the Secretary of
18 Health and Human Services, in consultation
19 with the Attorney General, has determined,
20 based on relevant scientific studies and nec-
21 essary data gathered by the Secretary of Health
22 and Human Services and gathered by the At-
23 torney General, that a drug or other substance
24 that has been temporarily placed in schedule A
25 does not have sufficient potential for abuse to

warrant control in any schedule, and provides a 30-day written notice of such determination to the Attorney General, the Attorney General—

“(i) may not issue a permanent scheduling order under subparagraph (A); and

“(ii) not later than 30 days after the date on which the Attorney General receives such notice, shall issue an order immediately terminating the temporary scheduling order for the drug or other substance.

“(6) NOTICE TO HHS.—Before initiating proceedings under paragraph (1), the Attorney General shall transmit notice of a temporary order proposed to be issued to the Secretary of Health and Human Services. In issuing an order under paragraph (1), the Attorney General shall take into consideration any comments submitted by the Secretary of Health and Human Services in response to a notice transmitted pursuant to this paragraph.”.

SEC. 4. PENALTIES.

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

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

4 (2) in subsection (b), by adding at the end the
5 following:

6 “(8) In the case of a violation under subsection (a)
7 involving a controlled substance in schedule A, the person
8 committing such violation shall be sentenced to a term of
9 imprisonment of not more than 20 years and if death or
10 serious bodily injury results from the use of such sub-
11 stance shall be sentenced to a term of imprisonment for
12 any term of years or for life, a fine not to exceed the great-
13 er of that authorized in accordance with the provisions of
14 title 18, United States Code, or \$1,000,000 if the defend-
15 ant is an individual or \$5,000,000 if the defendant is other
16 than an individual, or both. If any person commits such
17 a violation after a prior conviction for a felony drug of-
18 fense has become final, such person shall be sentenced to
19 a term of imprisonment of not more than 30 years and
20 if death or serious bodily injury results from the use of
21 such substance shall be sentenced to a term of imprison-
22 ment for any term of years or for life, a fine not to exceed
23 the greater of twice that authorized in accordance with
24 the provisions of title 18, United States Code, or
25 \$2,000,000 if the defendant is an individual or

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

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

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

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

23 “(1) It shall be unlawful to import or export,
 24 with intent to manufacture, distribute, or dispense,
 25 a schedule A substance or product containing a

1 schedule A substance, unless the substance or prod-
2 uct bears a label clearly identifying a schedule A
3 substance or product containing a schedule A sub-
4 stance by the nomenclature used by the Inter-
5 national Union of Pure and Applied Chemistry
6 (IUPAC).

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

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

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

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

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

24 “(II) such product is being used ex-
25 clusively for purposes of a clinical trial

1 that is the subject of an effective investiga-
2 tional new drug application.”.

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

5 (1) in subsection (a)—

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

8 (B) by redesignating paragraph (17) as
9 paragraph (18); and

10 (C) by inserting after paragraph (16) the
11 following:

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

13 (2) in subsection (c)—

14 (A) in paragraph (1)—

15 (i) in subparagraph (B)(i), by striking
16 “(17)” and inserting “(18)”; and

17 (ii) in subparagraph (C), by inserting
18 “or (17)” after “paragraph (16)” each
19 place it appears; and

20 (B) in paragraph (2)(D), by striking
21 “(17)” and inserting “(18)”.

22 **SEC. 6. REGISTRATION REQUIREMENTS FOR SCHEDULE A**
23 **SUBSTANCES.**

24 (a) REGISTRATION REQUIREMENTS FOR IMPORTERS
25 AND EXPORTERS OF SCHEDULE A SUBSTANCES.—Sec-

1 tion 1008 of the Controlled Substances Import and Export
2 Act (21 U.S.C. 958) is amended by adding at the end the
3 following:

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

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

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

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

17 “(A) maintenance of effective controls against
18 diversion of particular controlled substances and any
19 controlled substance in schedule A compounded
20 therefrom into other than legitimate medical, sci-
21 entific, research, or industrial channels, by limiting
22 the importation and bulk manufacture of such con-
23 trolled substances to a number of establishments
24 which can produce an adequate and uninterrupted
25 supply of these substances under adequately com-

1 petitive conditions for legitimate medical, scientific,
2 research, and industrial purposes;

3 “(B) compliance with applicable State and local
4 law;

5 “(C) promotion of technical advances in the art
6 of manufacturing substances described in subpara-
7 graph (A) and the development of new substances;

8 “(D) prior conviction record of applicant under
9 Federal and State laws relating to the importation,
10 manufacture, distribution, or dispensing of sub-
11 stances described in subparagraph (A);

12 “(E) past experience in the importation and
13 manufacture of controlled substances, and the exist-
14 ence in the establishment of effective control against
15 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 import or export
19 a controlled substance in schedule I or II under subsection
20 (a), the applicant shall not be required to apply for a sepa-
21 rate registration under this subsection.”.

22 (b) RESEARCH ON SUBSTANCES NEWLY ADDED TO
23 SCHEDULE A.—Section 302(e) of the Controlled Sub-
24 stances Act (21 U.S.C. 822(e)) is amended by adding at
25 the end the following:

1 “(3)(A) If a person is conducting research on a sub-
2 stance at the time the substance is added to schedule A,
3 and such person, subject to an exemption that is in effect
4 for investigational use, for that person, under section 505
5 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
6 355) to the extent conduct with respect to such substance
7 is pursuant to such exemption.”.

8 (c) CONTINUATION OF RESEARCH ON SUBSTANCES
9 NEWLY ADDED TO SCHEDULE A.—Section 302(e) of the
10 Controlled Substances Act (21 U.S.C. 822(e)), as amend-
11 ed by subsection (b) of this section, is amended by adding
12 at the end the following:

13 “(B) 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 “(C) 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 “(D) Nothing in this paragraph shall be construed
 4 to alter the authority of the Attorney General to initiate
 5 proceedings to deny, suspend, or revoke any registration
 6 in 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 ceding 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.

○