

AMENDMENT TO
OFFERED BY M__ . _____

At the end of the Rules Committee Print, add the following (and make such conforming changes as may be necessary):

1 **TITLE II—HALT ALL LETHAL**
2 **TRAFFICKING OF FENTANYL**

3 **SEC. 201. SHORT TITLE.**

4 This title may be cited as the “Halt All Lethal Traf-
5 ficking of Fentanyl Act” or the “HALT Fentanyl Act”.

6 **SEC. 202. CLASS SCHEDULING OF FENTANYL-RELATED SUB-**
7 **STANCES.**

8 Section 202(c) of the Controlled Substances Act (21
9 U.S.C. 812(c)) is amended by adding at the end of sched-
10 ule I the following:

11 “(e)(1) Unless specifically exempted or unless listed
12 in another schedule, any material, compound, mixture, or
13 preparation which contains any quantity of a fentanyl-re-
14 lated substance, or which contains the salts, isomers, and
15 salts of isomers of a fentanyl-related substance whenever
16 the existence of such salts, isomers, and salts of isomers
17 is possible within the specific chemical designation.

1 “(2) For purposes of paragraph (1), except as pro-
2 vided in paragraph (3), the term ‘fentanyl-related sub-
3 stance’ means any substance that is structurally related
4 to fentanyl by 1 or more of the following modifications:

5 “(A) By replacement of the phenyl portion of
6 the phenethyl group by any monocycle, whether or
7 not further substituted in or on the monocycle.

8 “(B) By substitution in or on the phenethyl
9 group with alkyl, alkenyl, alkoxy, hydroxyl, halo,
10 haloalkyl, amino, or nitro groups.

11 “(C) By substitution in or on the piperidine
12 ring with alkyl, alkenyl, alkoxy, ester, ether,
13 hydroxyl, halo, haloalkyl, amino, or nitro groups.

14 “(D) By replacement of the aniline ring with
15 any aromatic monocycle whether or not further sub-
16 stituted in or on the aromatic monocycle.

17 “(E) By replacement of the N-propionyl group
18 with another acyl group.

19 “(3) A substance that satisfies the definition of the
20 term ‘fentanyl-related substance’ in paragraph (2) shall
21 nonetheless not be treated as a fentanyl-related substance
22 subject to this schedule if the substance—

23 “(A) is controlled by action of the Attorney
24 General under section 201; or

1 “(B) is otherwise expressly listed in a schedule
2 other than this schedule.

3 “(4)(A) The Attorney General may by order publish
4 in the Federal Register a list of substances that satisfy
5 the definition of the term ‘fentanyl-related substance’ in
6 paragraph (2).

7 “(B) The absence of a substance from a list published
8 under subparagraph (A) does not negate the control status
9 of the substance under this schedule if the substance satis-
10 fies the definition of the term ‘fentanyl-related substance’
11 in paragraph (2).”.

12 **SEC. 203. REGISTRATION REQUIREMENTS RELATED TO RE-**
13 **SEARCH.**

14 (a) ALTERNATIVE REGISTRATION PROCESS FOR
15 SCHEDULE I RESEARCH.—Section 303 of the Controlled
16 Substances Act (21 U.S.C. 823) is amended by adding at
17 the end the following:

18 “(1) SPECIAL PROVISIONS FOR PRACTITIONERS CON-
19 DUCTING CERTAIN RESEARCH WITH SCHEDULE I CON-
20 TROLLED SUBSTANCES.—

21 “(1) IN GENERAL.—Notwithstanding subsection
22 (f), a practitioner may conduct research described in
23 paragraph (2) of this subsection with 1 or more
24 schedule I substances in accordance with subpara-

1 graph (A) or (B) of paragraph (3) of this sub-
2 section.

3 “(2) RESEARCH SUBJECT TO EXPEDITED PRO-
4 CEDURES.—Research described in this paragraph is
5 research that—

6 “(A) is with respect to a drug that is the
7 subject of an investigational use exemption
8 under section 505(i) of the Federal Food, Drug,
9 and Cosmetic Act; or

10 “(B) is—

11 “(i) conducted by the Department of
12 Health and Human Services or the De-
13 partment of Veterans Affairs; or

14 “(ii) funded partly or entirely by a
15 grant, contract, cooperative agreement, or
16 other transaction from the Department of
17 Health and Human Services or the De-
18 partment of Veterans Affairs.

19 “(3) EXPEDITED PROCEDURES.—

20 “(A) RESEARCHER WITH A CURRENT
21 SCHEDULE I OR II RESEARCH REGISTRATION.—

22 “(i) IN GENERAL.—If a practitioner is
23 registered to conduct research with a con-
24 trolled substance in schedule I or II, the
25 practitioner may conduct research under

1 this subsection on and after the date that
2 is 30 days after the date on which the
3 practitioner sends a notice to the Attorney
4 General containing the following informa-
5 tion, with respect to each substance with
6 which the practitioner will conduct the re-
7 search:

8 “(I) The chemical name of the
9 substance.

10 “(II) The quantity of the sub-
11 stance to be used in the research.

12 “(III) Demonstration that the re-
13 search is in the category described in
14 paragraph (2), which demonstration
15 may be satisfied—

16 “(aa) in the case of a grant,
17 contract, cooperative agreement,
18 or other transaction, or intra-
19 mural research project, by identi-
20 fying the sponsoring agency and
21 supplying the number of the
22 grant, contract, cooperative
23 agreement, other transaction, or
24 project; or

1 “(bb) in the case of an ap-
2 plication under section 505(i) of
3 the Federal Food, Drug, and
4 Cosmetic Act, by supplying the
5 application number and the spon-
6 sor of record on the application.

7 “(IV) Demonstration that the re-
8 searcher is authorized to conduct re-
9 search with respect to the substance
10 under the laws of the State in which
11 the research will take place.

12 “(ii) VERIFICATION OF INFORMATION
13 BY HHS OR VA.—Upon request from the
14 Attorney General, the Secretary of Health
15 and Human Services or the Secretary of
16 Veterans Affairs, as appropriate, shall
17 verify information submitted by an appli-
18 cant under clause (i)(III).

19 “(B) RESEARCHER WITHOUT A CURRENT
20 SCHEDULE I OR II RESEARCH REGISTRATION.—

21 “(i) IN GENERAL.—If a practitioner is
22 not registered to conduct research with a
23 controlled substance in schedule I or II,
24 the practitioner may send a notice to the
25 Attorney General containing the informa-

1 tion listed in subparagraph (A)(i), with re-
2 spect to each substance with which the
3 practitioner will conduct the research.

4 “(ii) ATTORNEY GENERAL ACTION.—
5 The Attorney General shall—

6 “(I) treat notice received under
7 clause (i) as a sufficient application
8 for a research registration; and

9 “(II) not later than 45 days of
10 receiving such a notice that contains
11 all information required under sub-
12 paragraph (A)(i)—

13 “(aa) register the applicant;
14 or

15 “(bb) serve an order to show
16 cause upon the applicant in ac-
17 cordance with section 304(c).

18 “(4) ELECTRONIC SUBMISSIONS.—The Attorney
19 General shall provide a means to permit a practi-
20 tioner to submit a notification under paragraph (3)
21 electronically.

22 “(5) LIMITATION ON AMOUNTS.—A practitioner
23 conducting research with a schedule I substance
24 under this subsection may only possess the amounts
25 of schedule I substance identified in—

1 “(A) the notification to the Attorney Gen-
2 eral under paragraph (3); or

3 “(B) a supplemental notification that the
4 practitioner may send if the practitioner needs
5 additional amounts for the research, which sup-
6 plemental notification shall include—

7 “(i) the name of the practitioner;

8 “(ii) the additional quantity needed of
9 the substance; and

10 “(iii) an attestation that the research
11 to be conducted with the substance is con-
12 sistent with the scope of the research that
13 was the subject of the notification under
14 paragraph (3).

15 “(6) IMPORTATION AND EXPORTATION RE-
16 QUIREMENTS NOT AFFECTED.—Nothing in this sub-
17 section alters the requirements of part A of title III,
18 regarding the importation and exportation of con-
19 trolled substances.”.

20 (b) SEPARATE REGISTRATIONS NOT REQUIRED FOR
21 ADDITIONAL RESEARCHER IN SAME INSTITUTION.—Sec-
22 tion 302(c) of the Controlled Substances Act (21 U.S.C.
23 822(c)) is amended by adding at the end the following:

1 “(4) An agent or employee of a research insti-
2 tution that is conducting research with a controlled
3 substance if—

4 “(A) the agent or employee is acting with-
5 in the scope of the professional practice of the
6 agent or employee;

7 “(B) another agent or employee of the in-
8 stitution is registered to conduct research with
9 a controlled substance in the same schedule;

10 “(C) the researcher who is so registered—

11 “(i) informs the Attorney General of
12 the name, position title, and employing in-
13 stitution of the agent or employee who is
14 not separately registered;

15 “(ii) authorizes that agent or em-
16 ployee to perform research under the reg-
17 istration of the registered researcher; and

18 “(iii) affirms that any act taken by
19 that agent or employee involving a con-
20 trolled substance shall be attributable to
21 the registered researcher, as if the re-
22 searcher had directly committed the act,
23 for purposes of any proceeding under sec-
24 tion 304(a) to suspend or revoke the reg-
25 istration of the registered researcher; and

1 “(D) the Attorney General does not, within
2 30 days of receiving the information, authoriza-
3 tion, and affirmation described in subparagraph
4 (C), refuse, for a reason listed in section
5 304(a), to allow the agent or employee to pos-
6 sess the substance without a separate registra-
7 tion.”.

8 (c) SINGLE REGISTRATION FOR RELATED RESEARCH
9 SITES.—Section 302(e) of the Controlled Substances Act
10 (21 U.S.C. 822(e)) is amended by adding at the end the
11 following:

12 “(3)(A) Notwithstanding paragraph (1), a person
13 registered to conduct research with a controlled substance
14 under section 303(f) may conduct the research under a
15 single registration if—

16 “(i) the research occurs exclusively on sites all
17 of which are—

18 “(I) within the same city or county; and

19 “(II) under the control of the same institu-
20 tion, organization, or agency; and

21 “(ii) before commencing the research, the re-
22 searcher notifies the Attorney General of each site
23 where—

24 “(I) the research will be conducted; or

1 “(II) the controlled substance will be
2 stored or administered.

3 “(B) A site described in subparagraph (A) shall be
4 included in a registration described in that subparagraph
5 only if the researcher has notified the Attorney General
6 of the site—

7 “(i) in the application for the registration; or

8 “(ii) before the research is conducted, or before
9 the controlled substance is stored or administered, at
10 the site.

11 “(C) The Attorney General may, in consultation with
12 the Secretary, issue regulations addressing, with respect
13 to research sites described in subparagraph (A)—

14 “(i) the manner in which controlled substances
15 may be delivered to the research sites;

16 “(ii) the storage and security of controlled sub-
17 stances at the research sites;

18 “(iii) the maintenance of records for the re-
19 search sites; and

20 “(iv) any other matters necessary to ensure ef-
21 fective controls against diversion at the research
22 sites.”.

23 (d) NEW INSPECTION NOT REQUIRED IN CERTAIN
24 SITUATIONS.—Section 302(f) of the Controlled Sub-
25 stances Act (21 U.S.C. 822(f)) is amended—

1 (1) by striking “(f) The” and inserting “(f)(1)
2 The”;

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

4 “(2)(A) If a person is registered to conduct research
5 with a controlled substance and applies for a registration,
6 or for a modification of a registration, to conduct research
7 with a second controlled substance that is in the same
8 schedule as the first controlled substance, or is in a sched-
9 ule with a higher numerical designation than the schedule
10 of the first controlled substance, a new inspection by the
11 Attorney General of the registered location is not required.

12 “(B) Nothing in subparagraph (A) shall prohibit the
13 Attorney General from conducting an inspection that the
14 Attorney General determines necessary to ensure that a
15 registrant maintains effective controls against diversion.”.

16 (e) CONTINUATION OF RESEARCH ON SUBSTANCES
17 NEWLY ADDED TO SCHEDULE I.—Section 302 of the
18 Controlled Substances Act (21 U.S.C. 822) is amended
19 by adding at the end the following:

20 “(h) CONTINUATION OF RESEARCH ON SUBSTANCES
21 NEWLY ADDED TO SCHEDULE I.—If a person is con-
22 ducting research on a substance when the substance is
23 added to schedule I, and the person is already registered
24 to conduct research with a controlled substance in sched-
25 ule I—

1 “(1) not later than 90 days after the scheduling
2 of the newly scheduled substance, the person shall
3 submit a completed application for registration or
4 modification of existing registration, to conduct re-
5 search on the substance, in accordance with regula-
6 tions issued by the Attorney General for purposes of
7 this paragraph;

8 “(2) the person may, notwithstanding sub-
9 sections (a) and (b), continue to conduct the re-
10 search on the substance until—

11 “(A) the person withdraws the application
12 described in paragraph (1) of this subsection;
13 or

14 “(B) the Attorney General serves on the
15 person an order to show cause proposing the
16 denial of the application under section 304(c);

17 “(3) if the Attorney General serves an order to
18 show cause as described in paragraph (2)(B) and
19 the person requests a hearing, the hearing shall be
20 held on an expedited basis and not later than 45
21 days after the request is made, except that the hear-
22 ing may be held at a later time if so requested by
23 the person; and

24 “(4) if the person sends a copy of the applica-
25 tion described in paragraph (1) to a manufacturer or

1 distributor of the substance, receipt of the copy by
2 the manufacturer or distributor shall constitute suf-
3 ficient evidence that the person is authorized to re-
4 ceive the substance.”.

5 (f) TREATMENT OF CERTAIN MANUFACTURING AC-
6 TIVITIES AS COINCIDENT TO RESEARCH.—Section 302 of
7 the Controlled Substances Act (21 U.S.C. 822), as amend-
8 ed by subsection (e), is amended by adding at the end
9 the following:

10 “(i) TREATMENT OF CERTAIN MANUFACTURING AC-
11 TIVITIES AS COINCIDENT TO RESEARCH.—

12 “(1) IN GENERAL.—Except as provided in para-
13 graph (3), a person who is registered to perform re-
14 search on a controlled substance may perform manu-
15 facturing activities with small quantities of that sub-
16 stance, including activities described in paragraph
17 (2), without being required to obtain a manufac-
18 turing registration, if—

19 “(A) the activities are performed for the
20 purpose of the research; and

21 “(B) the activities and the quantities of
22 the substance involved in the activities are stat-
23 ed in—

24 “(i) a notification submitted to the
25 Attorney General under section 303(l);

1 “(ii) a research protocol filed with an
2 application for registration approval under
3 section 303(f); or

4 “(iii) a notification to the Attorney
5 General that includes—

6 “(I) the name of the registrant;
7 and

8 “(II) an attestation that the re-
9 search to be conducted with the small
10 quantities of manufactured substance
11 is consistent with the scope of the re-
12 search that is the basis for the reg-
13 istration.

14 “(2) ACTIVITIES INCLUDED.—Activities per-
15 mitted under paragraph (1) include—

16 “(A) processing the substance to create ex-
17 tracts, tinctures, oils, solutions, derivatives, or
18 other forms of the substance consistent with—

19 “(i) the information provided as part
20 of a notification submitted to the Attorney
21 General under section 303(l); or

22 “(ii) a research protocol filed with an
23 application for registration approval under
24 section 303(f); and

1 “(B) dosage form development studies per-
2 formed for the purpose of requesting an inves-
3 tigational new drug exemption under section
4 505(i) of the Federal Food, Drug, and Cos-
5 metic Act (21 U.S.C. 355(i)).

6 “(3) EXCEPTION REGARDING MARIHUANA.—
7 The authority under paragraph (1) to manufacture
8 substances does not include the authority to grow
9 marihuana.”.

10 (g) TRANSPARENCY REGARDING SPECIAL PROCE-
11 DURES.—Section 303 of the Controlled Substances Act
12 (21 U.S.C. 823), as amended by subsection (a), is amend-
13 ed by adding at the end the following:

14 “(m) TRANSPARENCY REGARDING SPECIAL PROCE-
15 DURES.—

16 “(1) IN GENERAL.—If the Attorney General de-
17 termines, with respect to a controlled substance, that
18 an application by a practitioner to conduct research
19 with the substance should be considered under a
20 process, or subject to criteria, different from the
21 process or criteria applicable to applications to con-
22 duct research with other controlled substances in the
23 same schedule, the Attorney General shall make
24 public, including by posting on the website of the
25 Drug Enforcement Administration—

1 “(A) the identities of all substances for
2 which such determinations have been made;

3 “(B) the process and criteria that shall be
4 applied to applications to conduct research with
5 those substances; and

6 “(C) how the process and criteria described
7 in subparagraph (B) differ from the process
8 and criteria applicable to applications to con-
9 duct research with other controlled substances
10 in the same schedule.

11 “(2) TIMING OF POSTING.—The Attorney Gen-
12 eral shall make information described in paragraph
13 (1) public upon making a determination described in
14 that paragraph, regardless of whether a practitioner
15 has submitted such an application at that time.”.

16 **SEC. 204. RULEMAKING.**

17 (a) INTERIM FINAL RULES.—The Attorney Gen-
18 eral—

19 (1) shall, not later than 1 year of the date of
20 enactment of this title, issue rules to implement this
21 title and the amendments made by this title; and

22 (2) may issue the rules under paragraph (1) as
23 interim final rules.

24 (b) PROCEDURE FOR FINAL RULE.—

1 (1) EFFECTIVENESS OF INTERIM FINAL
2 RULES.—A rule issued by the Attorney General as
3 an interim final rule under subsection (a) shall be-
4 come immediately effective as an interim final rule
5 without requiring the Attorney General to dem-
6 onstrate good cause therefor, notwithstanding sub-
7 paragraph (B) of section 553(b) of title 5, United
8 States Code.

9 (2) OPPORTUNITY FOR COMMENT AND HEAR-
10 ING.—An interim final rule issued under subsection
11 (a) shall give interested persons the opportunity to
12 comment and to request a hearing.

13 (3) FINAL RULE.—After the conclusion of such
14 proceedings, the Attorney General shall issue a final
15 rule to implement this title and the amendments
16 made by this title in accordance with section 553 of
17 title 5, United States Code.

