

AMENDMENT TO RULES COMMITTEE PRINT 117-

31

OFFERED BY MR. LATTA OF OHIO

Page 829, after line 23, add the following:

1 **TITLE V—HALT ALL LETHAL**
2 **TRAFFICKING OF FENTANYL**
3 **SEC. 20501. CLASS SCHEDULING OF FENTANYL-RELATED**
4 **SUBSTANCES.**

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

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

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

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

4 “(B) By substitution in or on the phenethyl
5 group with alkyl, alkenyl, alkoxy, hydroxy, halo,
6 haloalkyl, amino, or nitro groups.

7 “(C) By substitution in or on the piperidine
8 ring with alkyl, alkenyl, alkoxy, ester, ether,
9 hydroxy, halo, haloalkyl, amino, or nitro groups.

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

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

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

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

21 “(B) is otherwise expressly listed in a schedule
22 other than this schedule.

23 “(4)(A) The Attorney General may by order publish
24 in the Federal Register a list of substances that satisfy

1 the definition of the term ‘fentanyl-related substance’ in
2 paragraph (2).

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

8 **SEC. 20502. REGISTRATION REQUIREMENTS RELATED TO**
9 **RESEARCH.**

10 (a) **ALTERNATIVE REGISTRATION PROCESS FOR**
11 **SCHEDULE I RESEARCH.**—Section 303 of the Controlled
12 Substances Act (21 U.S.C. 823) is amended by adding at
13 the end the following:

14 “(1) **SPECIAL PROVISIONS FOR PRACTITIONERS CON-**
15 **DUCTING CERTAIN RESEARCH WITH SCHEDULE I CON-**
16 **TROLLED SUBSTANCES.**—

17 “(1) **IN GENERAL.**—Notwithstanding subsection
18 (f), a practitioner may conduct research described in
19 paragraph (2) of this subsection with 1 or more
20 schedule I substances in accordance with subpara-
21 graph (A) or (B) of paragraph (3) of this sub-
22 section.

23 “(2) **RESEARCH SUBJECT TO EXPEDITED PRO-**
24 **CEDURES.**—Research described in this paragraph is
25 research that—

1 “(A) is with respect to a drug that is the
2 subject of an investigational use exemption
3 under section 505(i) of the Federal Food, Drug,
4 and Cosmetic Act; or

5 “(B) is—

6 “(i) conducted by the Department of
7 Health and Human Services or the De-
8 partment of Veterans Affairs; or

9 “(ii) funded partly or entirely by a
10 grant, contract, cooperative agreement, or
11 other transaction from the Department of
12 Health and Human Services or the De-
13 partment of Veterans Affairs.

14 “(3) EXPEDITED PROCEDURES.—

15 “(A) RESEARCHER WITH A CURRENT
16 SCHEDULE I OR II RESEARCH REGISTRATION.—

17 “(i) IN GENERAL.—If a practitioner is
18 registered to conduct research with a con-
19 trolled substance in schedule I or II, the
20 practitioner may conduct research under
21 this subsection on and after the date that
22 is 30 days after the date on which the
23 practitioner sends a notice to the Attorney
24 General containing the following informa-
25 tion, with respect to each substance with

1 which the practitioner will conduct the re-
2 search:

3 “(I) The chemical name of the
4 substance.

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

7 “(III) Demonstration that the re-
8 search is in the category described in
9 paragraph (2), which demonstration
10 may be satisfied—

11 “(aa) in the case of a grant,
12 contract, cooperative agreement,
13 or other transaction, or intra-
14 mural research project, by identi-
15 fying the sponsoring agency and
16 supplying the number of the
17 grant, contract, cooperative
18 agreement, other transaction, or
19 project; or

20 “(bb) in the case of an ap-
21 plication under section 505(i) of
22 the Federal Food, Drug, and
23 Cosmetic Act, by supplying the
24 application number and the spon-
25 sor of record on the application.

1 “(IV) Demonstration that the re-
2 searcher is authorized to conduct re-
3 search with respect to the substance
4 under the laws of the State in which
5 the research will take place.

6 “(ii) VERIFICATION OF INFORMATION
7 BY HHS OR VA.—Upon request from the
8 Attorney General, the Secretary of Health
9 and Human Services or the Secretary of
10 Veterans Affairs, as appropriate, shall
11 verify information submitted by an appli-
12 cant under clause (i)(III).

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

15 “(i) IN GENERAL.—If a practitioner is
16 not registered to conduct research with a
17 controlled substance in schedule I or II,
18 the practitioner may send a notice to the
19 Attorney General containing the informa-
20 tion listed in subparagraph (A)(i), with re-
21 spect to each substance with which the
22 practitioner will conduct the research.

23 “(ii) ATTORNEY GENERAL ACTION.—
24 The Attorney General shall—

1 “(I) treat notice received under
2 clause (i) as a sufficient application
3 for a research registration; and

4 “(II) not later than 45 days of
5 receiving such a notice that contains
6 all information required under sub-
7 paragraph (A)(i)—

8 “(aa) register the applicant;
9 or

10 “(bb) serve an order to show
11 cause upon the applicant in ac-
12 cordance with section 304(c).

13 “(4) ELECTRONIC SUBMISSIONS.—The Attorney
14 General shall provide a means to permit a practi-
15 tioner to submit a notification under paragraph (3)
16 electronically.

17 “(5) LIMITATION ON AMOUNTS.—A practitioner
18 conducting research with a schedule I substance
19 under this subsection may only possess the amounts
20 of schedule I substance identified in—

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

23 “(B) a supplemental notification that the
24 practitioner may send if the practitioner needs

1 additional amounts for the research, which sup-
2 plemental notification shall include—

3 “(i) the name of the practitioner;

4 “(ii) the additional quantity needed of
5 the substance; and

6 “(iii) an attestation that the research
7 to be conducted with the substance is con-
8 sistent with the scope of the research that
9 was the subject of the notification under
10 paragraph (3).

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

16 (b) SEPARATE REGISTRATIONS NOT REQUIRED FOR
17 ADDITIONAL RESEARCHER IN SAME INSTITUTION.—Sec-
18 tion 302(c) of the Controlled Substances Act (21 U.S.C.
19 822(c)) is amended by adding at the end the following:

20 “(4) An agent or employee of a research insti-
21 tution that is conducting research with a controlled
22 substance if—

23 “(A) the agent or employee is acting with-
24 in the scope of the professional practice of the
25 agent or employee;

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

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

5 “(i) informs the Attorney General of
6 the name, position title, and employing in-
7 stitution of the agent or employee who is
8 not separately registered;

9 “(ii) authorizes that agent or em-
10 ployee to perform research under the reg-
11 istration of the registered researcher; and

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

20 “(D) the Attorney General does not, within
21 30 days of receiving the information, authoriza-
22 tion, and affirmation described in subparagraph
23 (C), refuse, for a reason listed in section
24 304(a), to allow the agent or employee to pos-

1 sess the substance without a separate registra-
2 tion.”.

3 (c) SINGLE REGISTRATION FOR RELATED RESEARCH
4 SITES.—Section 302(e) of the Controlled Substances Act
5 (21 U.S.C. 822(e)) is amended by adding at the end the
6 following:

7 “(3)(A) Notwithstanding paragraph (1), a person
8 registered to conduct research with a controlled substance
9 under section 303(f) may conduct the research under a
10 single registration if—

11 “(i) the research occurs exclusively on sites all
12 of which are—

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

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

16 “(ii) before commencing the research, the re-
17 searcher notifies the Attorney General of each site
18 where—

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

20 “(II) the controlled substance will be
21 stored or administered.

22 “(B) A site described in subparagraph (A) shall be
23 included in a registration described in that subparagraph
24 only if the researcher has notified the Attorney General
25 of the site—

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

2 “(ii) before the research is conducted, or before
3 the controlled substance is stored or administered, at
4 the site.

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

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

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

12 “(iii) the maintenance of records for the re-
13 search sites; and

14 “(iv) any other matters necessary to ensure ef-
15 fective controls against diversion at the research
16 sites.”.

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

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

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

23 “(2)(A) If a person is registered to conduct research
24 with a controlled substance and applies for a registration,
25 or for a modification of a registration, to conduct research

1 with a second controlled substance that is in the same
2 schedule as the first controlled substance, or is in a sched-
3 ule with a higher numerical designation than the schedule
4 of the first controlled substance, a new inspection by the
5 Attorney General of the registered location is not required.

6 “(B) Nothing in subparagraph (A) shall prohibit the
7 Attorney General from conducting an inspection that the
8 Attorney General determines necessary to ensure that a
9 registrant maintains effective controls against diversion.”.

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

14 “(h) CONTINUATION OF RESEARCH ON SUBSTANCES
15 NEWLY ADDED TO SCHEDULE I.—If a person is con-
16 ducting research on a substance when the substance is
17 added to schedule I, and the person is already registered
18 to conduct research with a controlled substance in sched-
19 ule I—

20 “(1) not later than 90 days after the scheduling
21 of the newly scheduled substance, the person shall
22 submit a completed application for registration or
23 modification of existing registration, to conduct re-
24 search on the substance, in accordance with regula-

1 tions issued by the Attorney General for purposes of
2 this paragraph;

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

6 “(A) the person withdraws the application
7 described in paragraph (1) of this subsection;
8 or

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

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

19 “(4) if the person sends a copy of the applica-
20 tion described in paragraph (1) to a manufacturer or
21 distributor of the substance, receipt of the copy by
22 the manufacturer or distributor shall constitute suf-
23 ficient evidence that the person is authorized to re-
24 ceive the substance.”.

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

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

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

15 “(A) the activities are performed for the
16 purpose of the research; and

17 “(B) the activities and the quantities of
18 the substance involved in the activities are stat-
19 ed in—

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

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

1 “(iii) a notification to the Attorney
2 General that includes—

3 “(I) the name of the registrant;
4 and

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

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

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

16 “(i) the information provided as part
17 of a notification submitted to the Attorney
18 General under section 303(l); or

19 “(ii) a research protocol filed with an
20 application for registration approval under
21 section 303(f); and

22 “(B) dosage form development studies per-
23 formed for the purpose of requesting an inves-
24 tigational new drug exemption under section

1 505(i) of the Federal Food, Drug, and Cos-
2 metic Act (21 U.S.C. 355(i)).

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

7 (g) TRANSPARENCY REGARDING SPECIAL PROCE-
8 DURES.—Section 303 of the Controlled Substances Act
9 (21 U.S.C. 823), as amended by subsection (a), is amend-
10 ed by adding at the end the following:

11 “(m) TRANSPARENCY REGARDING SPECIAL PROCE-
12 DURES.—

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

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

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

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

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

14 **SEC. 20503. RULEMAKING.**

15 (a) INTERIM FINAL RULES.—The Attorney Gen-
16 eral—

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

20 (2) may issue the rules under paragraph (1) as
21 interim final rules.

22 (b) PROCEDURE FOR FINAL RULE.—

23 (1) EFFECTIVENESS OF INTERIM FINAL
24 RULES.—A rule issued by the Attorney General as
25 an interim final rule under subsection (a) shall be-

1 come immediately effective as an interim final rule
2 without requiring the Attorney General to dem-
3 onstrate good cause therefor, notwithstanding sub-
4 paragraph (B) of section 553(b) of title 5, United
5 States Code.

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

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

