AMENDMENT TO RULES COMMITTEE PRINT 117-31

OFFERED BY MR. LATTA OF OHIO

Page 829, after line 23, add the following:

TITLE V—HALT ALL LETHAL TRAFFICKING OF FENTANYL

SEC. 20501. CLASS SCHEDULING OF FENTANYL-RELATED SUBSTANCES.

Section 202(c) of the Controlled Substances Act (21 U.S.C. 812(c)) is amended by adding at the end of schedule I the following:

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

“(2) For purposes of paragraph (1), except as provided in paragraph (3), the term ‘fentanyl-related substance’ means any substance that is structurally related to fentanyl by 1 or more of the following modifications:
“(A) By replacement of the phenyl portion of
the phenethyl group by any monocycle, whether or
not further substituted in or on the monocycle.

“(B) By substitution in or on the phenethyl

group with alkyl, alkenyl, alkoxy, hydroxy, halo,
haloalkyl, amino, or nitro groups.

“(C) By substitution in or on the piperidine

ring with alkyl, alkenyl, alkoxy, ester, ether,
hydroxy, halo, haloalkyl, amino, or nitro groups.

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

“(E) By replacement of the N–propionyl group
with another acyl group.

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

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

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

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

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

SEC. 20502. REGISTRATION REQUIREMENTS RELATED TO RESEARCH.

(a) Alternative Registration Process for Schedule I Research.—Section 303 of the Controlled Substances Act (21 U.S.C. 823) is amended by adding at the end the following:

“(l) Special Provisions for Practitioners Conducting Certain Research With Schedule I Controlled Substances.—

“(1) In general.—Notwithstanding subsection (f), a practitioner may conduct research described in paragraph (2) of this subsection with 1 or more schedule I substances in accordance with subparagraph (A) or (B) of paragraph (3) of this subsection.

“(2) Research subject to expedited procedures.—Research described in this paragraph is research that—
“(A) is with respect to a drug that is the subject of an investigational use exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act; or

“(B) is—

“(i) conducted by the Department of Health and Human Services or the Department of Veterans Affairs; or

“(ii) funded partly or entirely by a grant, contract, cooperative agreement, or other transaction from the Department of Health and Human Services or the Department of Veterans Affairs.

“(3) EXPEDITED PROCEDURES.—

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

“(i) IN GENERAL.—If a practitioner is registered to conduct research with a controlled substance in schedule I or II, the practitioner may conduct research under this subsection on and after the date that is 30 days after the date on which the practitioner sends a notice to the Attorney General containing the following information, with respect to each substance with
which the practitioner will conduct the re-
search:

“(I) The chemical name of the sub-
stance.

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

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

“(aa) in the case of a grant,
contract, cooperative agreement,
or other transaction, or intra-
mural research project, by identi-
fying the sponsoring agency and
supplying the number of the
grant, contract, cooperative
agreement, other transaction, or
project; or

“(bb) in the case of an ap-
lication under section 505(i) of
the Federal Food, Drug, and
Cosmetic Act, by supplying the
application number and the spon-
sor of record on the application.
“(IV) Demonstration that the researcher is authorized to conduct research with respect to the substance under the laws of the State in which the research will take place.

“(ii) Verification of Information by HHS or VA.—Upon request from the Attorney General, the Secretary of Health and Human Services or the Secretary of Veterans Affairs, as appropriate, shall verify information submitted by an applicant under clause (i)(III).

“(B) Researcher Without a Current Schedule I or II Research Registration.—

“(i) In general.—If a practitioner is not registered to conduct research with a controlled substance in schedule I or II, the practitioner may send a notice to the Attorney General containing the information listed in subparagraph (A)(i), with respect to each substance with which the practitioner will conduct the research.

“(ii) Attorney General Action.—The Attorney General shall—
“(I) treat notice received under clause (i) as a sufficient application for a research registration; and

“(II) not later than 45 days of receiving such a notice that contains all information required under subparagraph (A)(i)—

“(aa) register the applicant;

or

“(bb) serve an order to show cause upon the applicant in accordance with section 304(c).

“(4) ELECTRONIC SUBMISSIONS.—The Attorney General shall provide a means to permit a practitioner to submit a notification under paragraph (3) electronically.

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

“(A) the notification to the Attorney General under paragraph (3); or

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

“(i) the name of the practitioner;
“(ii) the additional quantity needed of
the substance; and
“(iii) an attestation that the research
to be conducted with the substance is con-
sistent with the scope of the research that
was the subject of the notification under
paragraph (3).

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

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

“(4) An agent or employee of a research instit-
tion that is conducting research with a controlled
substance if—

“(A) the agent or employee is acting within
the scope of the professional practice of the
agent or employee;
“(B) another agent or employee of the institution is registered to conduct research with a controlled substance in the same schedule;

“(C) the researcher who is so registered—
   “(i) informs the Attorney General of the name, position title, and employing institution of the agent or employee who is not separately registered;
   “(ii) authorizes that agent or employee to perform research under the registration of the registered researcher; and
   “(iii) affirms that any act taken by that agent or employee involving a controlled substance shall be attributable to the registered researcher, as if the researcher had directly committed the act, for purposes of any proceeding under section 304(a) to suspend or revoke the registration of the registered researcher; and

“(D) the Attorney General does not, within 30 days of receiving the information, authorization, and affirmation described in subparagraph (C), refuse, for a reason listed in section 304(a), to allow the agent or employee to pos-
(c) Single Registration for Related Research Sites.—Section 302(e) of the Controlled Substances Act (21 U.S.C. 822(e)) is amended by adding at the end the following:

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

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

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

“(II) under the control of the same institution, organization, or agency; and

“(ii) before commencing the research, the researcher notifies the Attorney General of each site where—

“(I) the research will be conducted; or

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

“(B) A site described in subparagraph (A) shall be included in a registration described in that subparagraph only if the researcher has notified the Attorney General of the site—
“(i) in the application for the registration; or
“(ii) before the research is conducted, or before
the controlled substance is stored or administered, at
the site.
“(C) The Attorney General may, in consultation with
the Secretary, issue regulations addressing, with respect
to research sites described in subparagraph (A)—
“(i) the manner in which controlled substances
may be delivered to the research sites;
“(ii) the storage and security of controlled sub-
stances at the research sites;
“(iii) the maintenance of records for the re-
search sites; and
“(iv) any other matters necessary to ensure ef-
effective controls against diversion at the research
sites.”.
(d) NEW INSPECTION NOT REQUIRED IN CERTAIN
SITUATIONS.—Section 302(f) of the Controlled Sub-
stances Act (21 U.S.C. 822(f)) is amended—
(1) by striking “(f) The” and inserting “(f)(1)
The”; and
(2) by adding at the end the following:
“(2)(A) If a person is registered to conduct research
with a controlled substance and applies for a registration,
or for a modification of a registration, to conduct research
with a second controlled substance that is in the same
schedule as the first controlled substance, or is in a sched-
ule with a higher numerical designation than the schedule
of the first controlled substance, a new inspection by the
Attorney General of the registered location is not required.

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

(c) Continuation of Research on Substances
Newly Added to Schedule I.—Section 302 of the
Controlled Substances Act (21 U.S.C. 822) is amended
by adding at the end the following:

“(h) Continuation of Research on Substances
Newly Added to Schedule I.—If a person is con-
ducting research on a substance when the substance is
added to schedule I, and the person is already registered
to conduct research with a controlled substance in sched-
ule I—

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

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

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

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

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

“(4) if the person sends a copy of the applica-
tion described in paragraph (1) to a manufacturer or
distributor of the substance, receipt of the copy by
the manufacturer or distributor shall constitute suf-
ficient evidence that the person is authorized to re-
ceive the substance.”.
(f) **TREATMENT OF CERTAIN MANUFACTURING ACTIVITIES AS COINCIDENT TO RESEARCH.**—Section 302 of the Controlled Substances Act (21 U.S.C. 822), as amended by subsection (e), is amended by adding at the end the following:

“(i) **TREATMENT OF CERTAIN MANUFACTURING ACTIVITIES AS COINCIDENT TO RESEARCH.**—

“(1) **IN GENERAL.**—Except as provided in paragraph (3), a person who is registered to perform research on a controlled substance may perform manufacturing activities with small quantities of that substance, including activities described in paragraph (2), without being required to obtain a manufacturing registration, if—

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

“(B) the activities and the quantities of the substance involved in the activities are stated in—

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

“(ii) a research protocol filed with an application for registration approval under section 303(f); or
“(iii) a notification to the Attorney General that includes—

“(I) the name of the registrant; and

“(II) an attestation that the research to be conducted with the small quantities of manufactured substance is consistent with the scope of the research that is the basis for the registration.

“(2) ACTIVITIES INCLUDED.—Activities permitted under paragraph (1) include—

“(A) processing the substance to create extracts, tinctures, oils, solutions, derivatives, or other forms of the substance consistent with—

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

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

“(B) dosage form development studies performed for the purpose of requesting an investigational new drug exemption under section
505(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(i)).

“(3) Exception regarding marihuana.—

The authority under paragraph (1) to manufacture substances does not include the authority to grow marihuana.”.

(g) Transparency regarding special procedures.—Section 303 of the Controlled Substances Act (21 U.S.C. 823), as amended by subsection (a), is amended by adding at the end the following:

“(m) Transparency regarding special procedures.—

“(1) In general.—If the Attorney General determines, with respect to a controlled substance, that an application by a practitioner to conduct research with the substance should be considered under a process, or subject to criteria, different from the process or criteria applicable to applications to conduct research with other controlled substances in the same schedule, the Attorney General shall make public, including by posting on the website of the Drug Enforcement Administration—

“(A) the identities of all substances for which such determinations have been made;
“(B) the process and criteria that shall be applied to applications to conduct research with those substances; and

“(C) how the process and criteria described in subparagraph (B) differ from the process and criteria applicable to applications to conduct research with other controlled substances in the same schedule.

“(2) Timing of posting.—The Attorney General shall make information described in paragraph (1) public upon making a determination described in that paragraph, regardless of whether a practitioner has submitted such an application at that time.”.

SEC. 20503. RULEMAKING.

(a) Interim Final Rules.—The Attorney General—

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

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

(b) Procedure for Final Rule.—

(1) Effectiveness of Interim Final Rules.—A rule issued by the Attorney General as an interim final rule under subsection (a) shall be-
come immediately effective as an interim final rule without requiring the Attorney General to demonstrate good cause therefor, notwithstanding subparagraph (B) of section 553(b) of title 5, United States Code.

(2) Opportunity for comment and hearing.—An interim final rule issued under subsection (a) shall give interested persons the opportunity to comment and to request a hearing.

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