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(Original Signature of Member)

118TH CONGRESS
1ST SESSION

H. R.

To amend the Controlled Substances Act with respect to the scheduling of fentanyl-related substances, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

Mr. GRIFFITH introduced the following bill; which was referred to the Committee on _____

A BILL

To amend the Controlled Substances Act with respect to the scheduling of fentanyl-related substances, 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.**

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

1 **SEC. 2. CLASS SCHEDULING OF FENTANYL-RELATED SUB-**
2 **STANCES.**

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

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

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

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

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

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

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

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

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

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

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

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

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

1 **SEC. 3. REGISTRATION REQUIREMENTS RELATED TO RE-**
2 **SEARCH.**

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

7 “(m) SPECIAL PROVISIONS FOR PRACTITIONERS
8 CONDUCTING CERTAIN RESEARCH WITH SCHEDULE I
9 CONTROLLED SUBSTANCES.—

10 “(1) IN GENERAL.—Notwithstanding subsection
11 (f), a practitioner may conduct research described in
12 paragraph (2) of this subsection with 1 or more
13 schedule I substances in accordance with subpara-
14 graph (A) or (B) of paragraph (3) of this sub-
15 section.

16 “(2) RESEARCH SUBJECT TO EXPEDITED PRO-
17 CEDURES.—Research described in this paragraph is
18 research that—

19 “(A) is with respect to a drug that is the
20 subject of an investigational use exemption
21 under section 505(i) of the Federal Food, Drug,
22 and Cosmetic Act; or

23 “(B) is—

24 “(i) conducted by the Department of
25 Health and Human Services or the De-
26 partment of Veterans Affairs; or

1 “(ii) funded partly or entirely by a
2 grant, contract, cooperative agreement, or
3 other transaction from the Department of
4 Health and Human Services or the De-
5 partment of Veterans Affairs.

6 “(3) EXPEDITED PROCEDURES.—

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

9 “(i) IN GENERAL.—If a practitioner is
10 registered to conduct research with a con-
11 trolled substance in schedule I or II, the
12 practitioner may conduct research under
13 this subsection on and after the date that
14 is 30 days after the date on which the
15 practitioner sends a notice to the Attorney
16 General containing the following informa-
17 tion, with respect to each substance with
18 which the practitioner will conduct the re-
19 search:

20 “(I) The chemical name of the
21 substance.

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

24 “(III) Demonstration that the re-
25 search is in the category described in

1 paragraph (2), which demonstration
2 may be satisfied—

3 “(aa) in the case of a grant,
4 contract, cooperative agreement,
5 or other transaction, or intra-
6 mural research project, by identi-
7 fying the sponsoring agency and
8 supplying the number of the
9 grant, contract, cooperative
10 agreement, other transaction, or
11 project; or

12 “(bb) in the case of an ap-
13 plication under section 505(i) of
14 the Federal Food, Drug, and
15 Cosmetic Act, by supplying the
16 application number and the spon-
17 sor of record on the application.

18 “(IV) Demonstration that the re-
19 searcher is authorized to conduct re-
20 search with respect to the substance
21 under the laws of the State in which
22 the research will take place.

23 “(ii) VERIFICATION OF INFORMATION
24 BY HHS OR VA.—Upon request from the
25 Attorney General, the Secretary of Health

1 and Human Services or the Secretary of
2 Veterans Affairs, as appropriate, shall
3 verify information submitted by an appli-
4 cant under clause (i)(III).

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

7 “(i) IN GENERAL.—If a practitioner is
8 not registered to conduct research with a
9 controlled substance in schedule I or II,
10 the practitioner may send a notice to the
11 Attorney General containing the informa-
12 tion listed in subparagraph (A)(i), with re-
13 spect to each substance with which the
14 practitioner will conduct the research.

15 “(ii) ATTORNEY GENERAL ACTION.—
16 The Attorney General shall—

17 “(I) treat notice received under
18 clause (i) as a sufficient application
19 for a research registration; and

20 “(II) not later than 45 days of
21 receiving such a notice that contains
22 all information required under sub-
23 paragraph (A)(i)—

24 “(aa) register the applicant;
25 or

1 “(bb) serve an order to show
2 cause upon the applicant in ac-
3 cordance with section 304(c).

4 “(4) ELECTRONIC SUBMISSIONS.—The Attorney
5 General shall provide a means to permit a practi-
6 tioner to submit a notification under paragraph (3)
7 electronically.

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

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

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

18 “(i) the name of the practitioner;

19 “(ii) the additional quantity needed of
20 the substance; and

21 “(iii) an attestation that the research
22 to be conducted with the substance is con-
23 sistent with the scope of the research that
24 was the subject of the notification under
25 paragraph (3).

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

6 (b) SEPARATE REGISTRATIONS NOT REQUIRED FOR
7 ADDITIONAL RESEARCHER IN SAME INSTITUTION.—Sec-
8 tion 302(c) of the Controlled Substances Act (21 U.S.C.
9 822(c)) is amended by adding at the end the following:

10 “(4) An agent or employee of a research insti-
11 tution that is conducting research with a controlled
12 substance if—

13 “(A) the agent or employee is acting with-
14 in the scope of the professional practice of the
15 agent or employee;

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

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

20 “(i) informs the Attorney General of
21 the name, position title, and employing in-
22 stitution of the agent or employee who is
23 not separately registered;

1 “(ii) authorizes that agent or em-
2 ployee to perform research under the reg-
3 istration of the registered researcher; and

4 “(iii) affirms that any act taken by
5 that agent or employee involving a con-
6 trolled substance shall be attributable to
7 the registered researcher, as if the re-
8 searcher had directly committed the act,
9 for purposes of any proceeding under sec-
10 tion 304(a) to suspend or revoke the reg-
11 istration of the registered researcher; and

12 “(D) the Attorney General does not, within
13 30 days of receiving the information, authoriza-
14 tion, and affirmation described in subparagraph
15 (C), refuse, for a reason listed in section
16 304(a), to allow the agent or employee to pos-
17 sess the substance without a separate registra-
18 tion.”.

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

23 “(3)(A) Notwithstanding paragraph (1), a person
24 registered to conduct research with a controlled substance

1 under section 303(f) may conduct the research under a
2 single registration if—

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

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

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

8 “(ii) before commencing the research, the re-
9 searcher notifies the Attorney General of each site
10 where—

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

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

14 “(B) A site described in subparagraph (A) shall be
15 included in a registration described in that subparagraph
16 only if the researcher has notified the Attorney General
17 of the site—

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

19 “(ii) before the research is conducted, or before
20 the controlled substance is stored or administered, at
21 the site.

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

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

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

5 “(iii) the maintenance of records for the re-
6 search sites; and

7 “(iv) any other matters necessary to ensure ef-
8 fective controls against diversion at the research
9 sites.”.

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

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

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

16 “(2)(A) If a person is registered to conduct research
17 with a controlled substance and applies for a registration,
18 or for a modification of a registration, to conduct research
19 with a second controlled substance that is in the same
20 schedule as the first controlled substance, or is in a sched-
21 ule with a higher numerical designation than the schedule
22 of the first controlled substance, a new inspection by the
23 Attorney General of the registered location is not required.

24 “(B) Nothing in subparagraph (A) shall prohibit the
25 Attorney General from conducting an inspection that the

1 Attorney General determines necessary to ensure that a
2 registrant maintains effective controls against diversion.”.

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

7 “(h) CONTINUATION OF RESEARCH ON SUBSTANCES
8 NEWLY ADDED TO SCHEDULE I.—If a person is con-
9 ducting research on a substance when the substance is
10 added to schedule I, and the person is already registered
11 to conduct research with a controlled substance in sched-
12 ule I—

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

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

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

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

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

11 “(4) if the person sends a copy of the applica-
12 tion described in paragraph (1) to a manufacturer or
13 distributor of the substance, receipt of the copy by
14 the manufacturer or distributor shall constitute suf-
15 ficient evidence that the person is authorized to re-
16 ceive the substance.”.

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

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

24 “(1) IN GENERAL.—Except as provided in para-
25 graph (3), a person who is registered to perform re-

1 search on a controlled substance may perform manu-
2 facturing activities with small quantities of that sub-
3 stance, including activities described in paragraph
4 (2), without being required to obtain a manufac-
5 turing registration, if—

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

8 “(B) the activities and the quantities of
9 the substance involved in the activities are stat-
10 ed in—

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

13 “(ii) a research protocol filed with an
14 application for registration approval under
15 section 303(f); or

16 “(iii) a notification to the Attorney
17 General that includes—

18 “(I) the name of the registrant;
19 and

20 “(II) an attestation that the re-
21 search to be conducted with the small
22 quantities of manufactured substance
23 is consistent with the scope of the re-
24 search that is the basis for the reg-
25 istration.

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

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

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

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

12 “(B) dosage form development studies per-
13 formed for the purpose of requesting an inves-
14 tigational new drug exemption under section
15 505(i) of the Federal Food, Drug, and Cos-
16 metic Act (21 U.S.C. 355(i)).

17 “(3) EXCEPTION REGARDING MARIHUANA.—
18 The authority under paragraph (1) to manufacture
19 substances does not include the authority to grow
20 marihuana.”.

21 (g) TRANSPARENCY REGARDING SPECIAL PROCE-
22 DURES.—Section 303 of the Controlled Substances Act
23 (21 U.S.C. 823), as amended by subsection (a), is amend-
24 ed by adding at the end the following:

1 “(n) TRANSPARENCY REGARDING SPECIAL PROCE-
2 DURES.—

3 “(1) IN GENERAL.—If the Attorney General de-
4 termines, with respect to a controlled substance, that
5 an application by a practitioner to conduct research
6 with the substance should be considered under a
7 process, or subject to criteria, different from the
8 process or criteria applicable to applications to con-
9 duct research with other controlled substances in the
10 same schedule, the Attorney General shall make
11 public, including by posting on the website of the
12 Drug Enforcement Administration—

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

15 “(B) the process and criteria that shall be
16 applied to applications to conduct research with
17 those substances; and

18 “(C) how the process and criteria described
19 in subparagraph (B) differ from the process
20 and criteria applicable to applications to con-
21 duct research with other controlled substances
22 in the same schedule.

23 “(2) TIMING OF POSTING.—The Attorney Gen-
24 eral shall make information described in paragraph
25 (1) public upon making a determination described in

1 that paragraph, regardless of whether a practitioner
2 has submitted such an application at that time.”.

3 **SEC. 4. RULEMAKING.**

4 (a) INTERIM FINAL RULES.—The Attorney Gen-
5 eral—

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

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

11 (b) PROCEDURE FOR FINAL RULE.—

12 (1) EFFECTIVENESS OF INTERIM FINAL
13 RULES.—A rule issued by the Attorney General as
14 an interim final rule under subsection (a) shall be-
15 come immediately effective as an interim final rule
16 without requiring the Attorney General to dem-
17 onstrate good cause therefor, notwithstanding sub-
18 paragraph (B) of section 553(b) of title 5, United
19 States Code.

20 (2) OPPORTUNITY FOR COMMENT AND HEAR-
21 ING.—An interim final rule issued under subsection
22 (a) shall give interested persons the opportunity to
23 comment and to request a hearing.

24 (3) FINAL RULE.—After the conclusion of such
25 proceedings, the Attorney General shall issue a final

1 rule to implement this Act and the amendments
2 made by this Act in accordance with section 553 of
3 title 5, United States Code.