AMENDMENT TO

RULES COMMITTEE PRINT 117–31

OFFERED BY MR. LUETKEMEYER OF MISSOURI

At the end of division C of the Rules Committee Print, add the following new title:

TITLE V—STOPPING ILLICIT TRAFFICKING

SEC. 20501. FENTANYL-RELATED SUBSTANCES.

Section 202(c) of the Controlled Substances Act (21 U.S.C. 812) is amended—

(1) by adding at the end of subsection (b) of Schedule I the following:

''(23) Isobutyryl fentanyl.

''(24) Para-Methoxybutyrylfentanyl.

''(25) Valeryl fentanyl.

''(26) Cyclopentyl fentanyl.

''(27) Para-Chloroisobutyryl fentanyl.''; and

(2) 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 fentanyl-related substances, or which contains their salts, isomers,

and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

''(2) In paragraph (1), the term 'fentanyl-related substances' includes the following:

''(A) Any substance that is structurally related to fentanyl by one or more of the following modifications:

''(i) By replacement of the phenyl portion of the phenethyl group by any monocycle, whether or not further substituted in or on the monocycle.

''(ii) By substitution in or on the phenethyl group with alkyl, alkenyl, alkoxy, hydroxy, halo, haloalkyl, amino or nitro groups.

''(iii) By substitution in or on the piperidine ring with alkyl, alkenyl, alkoxy, ester, ether, hydroxy, halo, haloalkyl, amino or nitro groups.

''(iv) By replacement of the aniline ring with any aromatic monocycle whether or not further substituted in or on the aromatic monocycle.

''(v) By replacement of the N-propionyl group by another acyl group.

''(B) 4′-Methyl acetyl fentanyl.

''(C) Crotonyl fentanyl.

''(D) 2′-Fluoro ortho-fluorofentanyl.

''(E) Ortho-Methyl acetylfentanyl.

''(F) Thiofuranyl fentanyl.

''(G) Ortho-Fluorobutyryl fentanyl.

''(H) Ortho-Fluoroacryl fentanyl.

''(I) Beta-Methyl fentanyl.

''(J) Phenyl fentanyl.

''(K) Para-Methylfentanyl.

''(L) Beta′-Phenyl fentanyl.

''(M) Benzodioxole fentanyl.''.

SEC. 20502. REMOVAL FROM SCHEDULE I(e) OF FENTANYL-RELATED SUBSTANCES.

Section 201 of the Controlled Substances Act (21 U.S.C. 811) is amended by adding at the end the following new subsection:

''(k)(1) If the Secretary finds, based on the factors specified in paragraph (4), that a substance listed in schedule I(e) has no potential for abuse, the Secretary shall—

''(A) notify the Attorney General at least 90 days prior to submitting an evaluation scientific and medical evaluation of that substance supporting that conclusion; and

''(B) submit to the Attorney General such evaluation and conclusion that—

''(i) is in writing; and

''(ii) includes the bases for such conclusion.

''(2) Not later than 90 days after the receipt of such evaluation and conclusion, the Attorney General shall issue an order removing such substance from the schedule.

''(3)(A) If the Secretary finds, based on the factors specified in paragraph (4), that a substance listed in schedule I(e) does not meet the requirements for inclusion in that schedule, and that the substance has a low potential for abuse, the Secretary shall submit to the Attorney General a scientific and medical evaluation of that substance supporting those conclusions that is in writing and that includes the bases for that conclusion.

''(B) Within 180 days of receipt of such evaluation and conclusion, the Attorney General shall—

''(i) issue an order removing such substance from scheduling for research purposes only, or

''(ii) notify the Secretary in writing that the Attorney General declines to issue such an order.

''(4) In making the evaluation and conclusion described in paragraph (1) or (3), the Secretary—

''(A) shall consider the factors specified in paragraphs (1), (2), (3), and (6) of subsection (c) and any information submitted to the Attorney General under paragraph (1) of this subsection; and

''(B) may also consider factors specified in paragraphs (4), (5), and (7) of subsection (c) if the Secretary finds that reliable evidence exists with respect to such factors.

''(5) Nothing in this subsection shall preclude the Attorney General from transferring a substance listed in schedule I to another schedule, or removing such substance entirely from the schedules, pursuant to other provisions of this section or section 202.

''(6) A substance removed from schedule I(e) pursuant to paragraph (1) or (3) may, at any time, be controlled pursuant to the other provisions of this section or section 202 without regard to that removal.''.

SEC. 20503. CLARIFICATION OF CERTAIN REGISTRATION REQUIREMENTS RELATED TO RESEARCH.

(a) EXCEPTION FOR AGENTS OR EMPLOYEES OF REGISTERED RESEARCHERS.—Section 302(c)(1) of the Controlled Substances Act (21 U.S.C. 822(c)(1)) is amended by striking ''or dispenser'' and inserting ''dispenser, or researcher''.

(b) CONFORMING AMENDMENT.—Section 102(3) of the Controlled Substances Act (21 U.S.C. 802(3)) is amended by striking ''or dispenser'' and inserting ''dispenser, or researcher.''

(c) SINGLE REGISTRATION FOR CONTIGUOUS 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 new paragraph:

''(3) Notwithstanding paragraph (1), a person registered to conduct research with a controlled substance under section 303(f) may conduct such research under a single registration if such research occurs exclusively on a single, contiguous campus and the registrant notifies the Attorney General in writing of all sites on the campus where the research will be conducted or where the controlled substance will be stored or administered. If the registrant seeks to conduct such research at additional sites, the registrant shall submit a new notification before conducting such research at any such additional sites.''.

(d) NEW INSPECTION NOT REQUIRED IN CERTAIN SITUATIONS.—Section 303(f) of the Controlled Substances Act (21 U.S.C. 823(f)) is amended—

(1) by redesignating paragraphs (1) through (5) as subparagraphs (A) through (E), respectively, and by moving the margins of such subparagraphs (as so redesignated) two ems to the right;

(2) by striking ''(f) The'' and inserting ''(f)(1) The''; and

(3) by adding at the end the following new paragraph:

''(2)(A) If a person is registered to conduct research with a controlled substance and applies to be registered, or to modify a registration to conduct research with a second controlled substance that is in the same schedule or in a schedule with a higher numerical designation, a new inspection by the Attorney General of the registered location is not required.

''(B) Nothing in this paragraph shall prohibit the Attorney General from conducting any inspection if the Attorney General determines such an inspection is necessary.''.

(e) CONTINUATION OF RESEARCH ON NEWLY ADDED SUBSTANCES; AUTHORITY TO CONDUCT RESEARCH WITH OTHER SUBSTANCES.—Section 302 of the Controlled Substances Act (21 U.S.C. 822), as amended by subsections (a) and (c), is further amended by adding at the end the following new subsection:

''(h)(1) In the case of a person who is conducting research on a substance at the time the substance is added to schedule I and who is already registered to conduct research with another controlled substance in schedule I or II, the person—

''(A) within 30 days of the scheduling of such substance, shall submit a completed application for registration or modification of the existing registration of such person, to conduct research on such substance, in accordance with the regulations issued by the Attorney General; and

''(B) notwithstanding subsections (a) and (b), may continue to conduct the research on such substance until the date on which—

''(i) the application referred to in subparagraph (A) is withdrawn by the applicant; or

''(ii) the Attorney General serves on the applicant an order to show cause proposing the denial of the application pursuant to section 304(c).

''(2) If the Attorney General serves an order to show cause under paragraph (1)(B) and the applicant requests a hearing, such hearing shall be held—

''(A) on an expedited basis; and

''(B) not later than 45 days after the request is made, or such a later time as requested by the applicant.

''(3)(A) A person who is registered to conduct research with a controlled substance in schedule I may, notwithstanding subsections (a) and (b), conduct research with another controlled substance in schedule I, if each of following conditions are met:

''(i) The person has applied for a modification of the person's registration to authorize research with such other controlled substance in accordance with the regulations issued by the Attorney General.

''(ii) The Attorney General has obtained verification from the Secretary that the research protocol submitted with the application is meritorious.

''(iii) The Attorney General has determined under subparagraph (B) that the conduct of such research is consistent with United States obligations under the Single Convention on Narcotic Drugs, 1961.

''(B) Not later than 30 days after receiving an application under clause (i), the Attorney General shall determine whether the conduct of research that is the subject of the application is consistent with United States obliga-

tions under the Single Convention on Narcotic Drugs, 1961.

''(C) Nothing in this section shall be construed to alter the authority of the Attorney General to initiate proceedings to deny, suspend, or revoke any registration in accordance with sections 303 and 304.''.

(f) TREATMENT OF CERTAIN ACTIVITIES AS COINCIDENT TO RESEARCH.—Section 302 of the Controlled Substances Act (21 U.S.C. 822), as amended by subsections (a), (c), and (e), is further amended by adding at the end the following new subsection:

''(i) A person who is registered to perform research with a controlled substance (other than marihuana) under this title may, without being required to registered to manufacture such substance, using small quantities of such substance, perform the following activities:

''(1) Processing the substance to create extracts, tinctures, oils, solutions, derivatives, or other forms of the substance consistent with the approved research protocol.

''(2) Dosage form development for the purpose of satisfying requirements with respect to the submission of an investigational new drug application under section 505(i) of the Federal Food, Drug, and Cosmetic Act.''.

SEC. 20504. REVIEW OF RESEARCH REGISTRATION PROCESS.

(a) REVIEW.—Not later than one year after the date of the enactment of this section, the Attorney General and the Secretary of Health and Human Services shall jointly conduct a review of the processes used to register or modify a registration to conduct research with controlled substances under the Controlled Substances Act (21 U.S.C. 801 et seq.), including—

(1) an evaluation of the impacts of the amendments made by this title on the risk of the diversion of controlled substances used in research and related public safety considerations; and

(2) an identification of opportunities to reduce any unnecessary burden on persons seeking registration, potential redundancies, and inefficiencies in such processes, including—

(A) the process for obtaining a registration under section 303 of the Controlled Substances Act (21 U.S.C. 823); and

(B) the process by which the Secretary reviews research protocols submitted with respect to such registration.

(b) GUIDANCE.—Not later than 60 days after concluding the review described in subsection (a), the Attorney General and the Secretary shall, as appropriate, joint-

ly issue guidance to registrants and potential registrants clarifying the process for registration.

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