118TH CONGRESS
1st Session
HOUSE OF REPRESENTATIVES
REPT. 118–67
Part 1

HALT ALL LETHAL TRAFFICKING OF FENTANYL ACT

MAY 17, 2023.—Committed to the Committee of the Whole House on the State of the Union and ordered to be printed

Mrs. RODGERS of Washington, from the Committee on Energy and Commerce, submitted the following

R E P O R T

together with

MINORITY VIEWS

[To accompany H.R. 467]

The Committee on Energy and Commerce, to whom was referred the bill (H.R. 467) to amend the Controlled Substances Act with respect to the scheduling of fentanyl-related substances, and for other purposes, having considered the same, reports favorably thereon with an amendment and recommends that the bill as amended do pass.

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39–006

The amendment is as follows:
Strike all after the enacting clause and insert the following:

SECTION 1. SHORT TITLE.

This Act may be cited as the "Halt All Lethal Trafficking of Fentanyl Act" or the "HALT Fentanyl Act".

SEC. 2. 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, alkoxyl, hydroxyl, halo, haloalkyl, amino, or nitro groups.

"(C) By substitution in or on the piperidine ring with alkyl, alkenyl, alkoxyl, ester, ether, hydroxyl, halo, haloalkyl, amino, or nitro groups.

"(D) By replacement of the aniline ring with any aromatic monocycle whether or not further substituted 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. 3. 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—

(1) by redesignating the second subsection (l) (relating to required training for prescribers) as subsection (m); and

(2) by adding at the end the following:

"(n) 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 research:

"(I) The chemical name of the substance.

"(II) The quantity of the substance to be used in the research.

"(III) Demonstration that the research 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 intramural research project, by identifying the sponsoring agency and supplying the number of the grant, contract, cooperative agreement, other transaction, or project; or

"(bb) in the case of an application under section 505(i) of the Federal Food, Drug, and Cosmetic Act, by supplying the application number and the sponsor 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 supplemental 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 consistent with the scope of the research that was the subject of the notification under paragraph (3).

"(6) IMPORTATION AND EXPORTATION REQUIREMENTS NOT AFFECTED.—Nothing in this subsection alters the requirements of part A of title III, regarding the importation and exportation of controlled substances.".

(b) SEPARATE REGISTRATIONS NOT REQUIRED FOR ADDITIONAL RESEARCHER IN SAME INSTITUTION.—Section 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 institution 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 possess the substance without a separate registration.".

(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:

"(4)(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 substances at the research sites;

"(iii) the maintenance of records for the research sites; and

"(iv) any other matters necessary to ensure effective controls against diversion at the research sites.".

(d) NEW INSPECTION NOT REQUIRED IN CERTAIN SITUATIONS.—Section 302(f) of the Controlled Substances 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 schedule 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.".

(e) 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 conducting 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 schedule 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 research on the substance, in accordance with regulations issued by the Attorney General for purposes of this paragraph;

"(2) the person may, notwithstanding subsections (a) and (b), continue to conduct the research 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 hearing may be held at a later time if so requested by the person; and

"(4) if the person sends a copy of the application described in paragraph (1) to a manufacturer or distributor of the substance, receipt of the copy by the manufacturer or distributor shall constitute sufficient evidence that the person is authorized to receive 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:

"(o) 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. 4. 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 become 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.

SEC. 5. PENALTIES.

(a) IN GENERAL.—Section 401(b)(1) of the Controlled Substances Act (21 U.S.C. 841(b)(1)) is amended—

(1) in subparagraph (A)(vi), by inserting "or a fentanyl-related substance" after "any analogue of N-phenyl-N-[1-(2-phenylethyl)-4-piperidinyl] propanamide"; and

(2) in subparagraph (B)(vi), by inserting "or a fentanyl-related substance" after "any analogue of N-phenyl-N-[1-(2-phenylethyl)-4-piperidinyl] propanamide".

(b) IMPORTATION AND EXPORTATION.—Section 1010(b) of the Controlled Substances Import and Export Act (21 U.S.C. 960(b)) is amended—

(1) in paragraph (1)(F), by inserting "or a fentanyl-related substance" after "any analogue of N-phenyl-N-[1-(2-phenylethyl)-4-piperidinyl] propanamide"; and

(2) in paragraph (2)(F), by inserting "or a fentanyl-related substance" after "any analogue of N-phenyl-N-[1-(2-phenylethyl)-4-piperidinyl] propanamide".

SEC. 6. APPLICABILITY; OTHER MATTERS.

(a) IN GENERAL.—Irrespective of the date on which the rules required by section 4 are finalized, the amendments made by this Act apply beginning as of the enactment of this Act.

(b) RULE OF CONSTRUCTION.—Nothing in the amendments made by this Act may be construed as evidence that, in applying sections 401(b)(1) and 1010(b) of the Controlled Substances Act (21 U.S.C. 841(b)(1) and 960(b)) with respect to conduct occurring before the date of the enactment of this Act, a fentanyl-related substance (as defined by such amendments) is not an analogue of N-phenyl-N-[1-(2-phenylethyl)-4-piperidinyl] propanamide.

(c) SENSE OF CONGRESS.—The Congress agrees with the interpretation of the Controlled Substances Act (21 U.S.C. 801 et seq.) in *United States v. McCray*, 346 F. Supp. 3d 363 (2018).

PURPOSE AND SUMMARY

H.R. 467 amends the Controlled Substances Act (CSA) to permanently place fentanyl related substances (FRS) into schedule 1. The legislation also amends the Drug Enforcement Administration (DEA) registration process for schedule 1 drugs to align them with the schedule 2 process, making it easier to conduct studies on these substances. It also requires the DEA to conduct a rulemaking.

BACKGROUND AND NEED FOR LEGISLATION

In 2021, nearly 108,000 people died of drug overdoses; 71,000 of which were from fentanyl or fentanyl-related substances. FRS are substances that have a similar chemical structure to fentanyl, but are not identical. FRS have no known medical use and have a high potential for abuse, which is why they belong in schedule 1. FRS are currently subject to an emergency scheduling order that is set to expire on December 31, 2024. If this scheduling order expires,

FRS would become legal. Permanently placing FRS into schedule 1 of the CSA would halt the creation of new FRS and decrease the amount of these deadly substances that are found on our streets. DEA has said that this is its top legislative priority.

COMMITTEE ACTION

On February 1, 2023, the Subcommittee on Health held a hearing on H.R. 467. The Subcommittee received testimony from:

- Mr. Kemp Chester, Senior Advisor, International Relations and Supply Reduction, Office of National Drug Control Policy (ONDCP)
- Dr. Neeraj Gandotra, Chief Medical Officer, Substance Abuse and Mental Health Services Administration (SAMHSA)
- Mr. Jon C. DeLena, Associate Administrator, Business Operations, Drug Enforcement Administration (DEA)
- Ms. Kandi Pickard, President and CEO, National Down Syndrome Society (NDSS)
- Mr. Frederick Isasi, J.D. MPH, Executive Director, Families USA
- Ms. Molly Cain, Parent Advocate
- Dr. Stephen Loyd, MD, Chief Medical Officer, Cedar Recovery
- Dr. Timothy Westlake, MD, Emergency Medicine Physician

On March 8, 2023, the Subcommittee on Health met in open markup session and forwarded H.R. 467, as amended, to the full Committee by a record vote of 17 yeas and 10 nays. On March 24, 2023, the full Committee on Energy and Commerce met in open markup session and ordered H.R. 467, as amended, favorably reported to the House by a record vote of 27 yeas and 19 nays.

COMMITTEE VOTES

Clause 3(b) of rule XIII requires the Committee to list the record votes on the motion to report legislation and amendments thereto. The following reflects the record votes taken during the Committee consideration:

COMMITTEE ON ENERGY AND COMMERCE
118TH CONGRESS
ROLL CALL VOTE #19

BILL: H.R. 467, the Halt All Lethal Trafficking of Fentanyl Act

AMENDMENT: An amendment in the nature of a substitute offered by Mr. Pallone, No. 1.

DISPOSITION: NOT AGREED TO, by a roll call vote of 20 yeas and 24 nays.

REPRESENTATIVE	YEAS	NAYS	PRESENT	REPRESENTATIVE	YEAS	NAYS	PRESENT
Rep. Rodgers		X		Rep. Pallone	X		
Rep. Burgess		X		Rep. Eshoo	X		
Rep. Latta		X		Rep. DeGette	X		
Rep. Guthrie		X		Rep. Schakowsky	X		
Rep. Griffith		X		Rep. Matsui	X		
Rep. Bilirakis		X		Rep. Castor			
Rep. Johnson		X		Rep. Sarbanes	X		
Rep. Bucshon				Rep. Tonko	X		
Rep. Hudson				Rep. Clarke	X		
Rep. Walberg		X		Rep. Cárdenas			
Rep. Carter		X		Rep. Ruiz	X		
Rep. Duncan		X		Rep. Peters	X		
Rep. Palmer				Rep. Dingell	X		
Rep. Dunn		X		Rep. Veasey	X		
Rep. Curtis		X		Rep. Kuster	X		
Rep. Lesko		X		Rep. Kelly			
Rep. Pence				Rep. Barragán	X		
Rep. Crenshaw		X		Rep. Blunt Rochester	X		
Rep. Joyce		X		Rep. Soto	X		
Rep. Armstrong		X		Rep. Craig	X		
Rep. Weber		X		Rep. Schrier	X		
Rep. Allen		X		Rep. Trahan	X		
Rep. Balderson		X		Rep. Fletcher	X		
Rep. Fulcher		X					
Rep. Pfluger							
Rep. Harshbarger		X					
Rep. Miller-Meeks		X					
Rep. Cammack		X					
Rep. Obernolte		X					

03/24/2023

COMMITTEE ON ENERGY AND COMMERCE
118TH CONGRESS
ROLL CALL VOTE #20

BILL: H.R. 467, the Halt All Lethal Trafficking of Fentanyl Act

AMENDMENT: A motion by Mrs. Rodgers to order H.R. 467 favorably reported to the House, as amended (Final Passage).

DISPOSITION: **AGREED TO,** by a roll call vote of 27 yeas and 19 nays.

REPRESENTATIVE	YEAS	NAYS	PRESENT	REPRESENTATIVE	YEAS	NAYS	PRESENT
Rep. Rodgers	X			Rep. Pallone		X	
Rep. Burgess	X			Rep. Eshoo		X	
Rep. Latta	X			Rep. DeGette		X	
Rep. Guthrie	X			Rep. Schakowsky		X	
Rep. Griffith	X			Rep. Matsui		X	
Rep. Bilirakis	X			Rep. Castor			
Rep. Johnson	X			Rep. Sarbanes		X	
Rep. Bucshon				Rep. Tonko		X	
Rep. Hudson				Rep. Clarke		X	
Rep. Walberg	X			Rep. Cárdenas		X	
Rep. Carter	X			Rep. Ruiz		X	
Rep. Duncan	X			Rep. Peters		X	
Rep. Palmer				Rep. Dingell		X	
Rep. Dunn	X			Rep. Veasey		X	
Rep. Curtis	X			Rep. Kuster		X	
Rep. Lesko	X			Rep. Kelly			
Rep. Pence				Rep. Barragán		X	
Rep. Crenshaw	X			Rep. Blunt Rochester		X	
Rep. Joyce	X			Rep. Soto		X	
Rep. Armstrong	X			Rep. Craig	X		
Rep. Weber	X			Rep. Schrier	X		
Rep. Allen	X			Rep. Trahan		X	
Rep. Balderson	X			Rep. Fletcher		X	
Rep. Fulcher	X						
Rep. Pfluger	X						
Rep. Harshbarger	X						
Rep. Miller-Meeks	X						
Rep. Cammack	X						
Rep. Obernolte	X						

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OVERSIGHT FINDINGS AND RECOMMENDATIONS

Pursuant to clause 2(b)(1) of rule X and clause 3(c)(1) of rule XIII, the Committee held a hearing and made findings that are reflected in this report.

NEW BUDGET AUTHORITY, ENTITLEMENT AUTHORITY, AND TAX EXPENDITURES

Pursuant to clause 3(c)(2) of rule XIII, the Committee finds that H.R. 467 would result in no new or increased budget authority, entitlement authority, or tax expenditures or revenues.

CONGRESSIONAL BUDGET OFFICE ESTIMATE

Pursuant to clause 3(c)(3) of rule XIII, at the time this report was filed, the cost estimate prepared by the Director of the Congressional Budget Office pursuant to section 402 of the Congressional Budget Act of 1974 was not available.

FEDERAL MANDATES STATEMENT

The Committee adopts as its own the estimate of Federal mandates prepared by the Director of the Congressional Budget Office pursuant to section 423 of the Unfunded Mandates Reform Act.

STATEMENT OF GENERAL PERFORMANCE GOALS AND OBJECTIVES

Pursuant to clause 3(c)(4) of rule XIII, the general performance goal or objective of this legislation is to place FRS into schedule 1 of the CSA permanently and to streamline the DEA registration process for schedule 1 drugs so researchers can conduct studies on these substances.

DUPLICATION OF FEDERAL PROGRAMS

Pursuant to clause 3(c)(5) of rule XIII, no provision of H.R. 467 is known to be duplicative of another Federal program, including any program that was included in a report to Congress pursuant to section 21 of Public Law 111–139 or the most recent Catalog of Federal Domestic Assistance.

RELATED COMMITTEE AND SUBCOMMITTEE HEARINGS

Pursuant to clause 3(c)(6) of rule XIII,

(1) the following related hearing was used to develop or consider H.R. 467:

On February 1, 2023, the Subcommittee on Health held a hearing on H.R. 467. The Subcommittee received testimony from:

- Mr. Kemp Chester, Senior Advisor, International Relations and Supply Reduction, Office of National Drug Control Policy (ONDCP)
- Dr. Neeraj Gandotra, Chief Medical Officer, Substance Abuse and Mental Health Services Administration (SAMHSA)
- Mr. Jon C. DeLena, Associate Administrator, Business Operations, Drug Enforcement Administration (DEA)
- Ms. Kandi Pickard, President and CEO, National Down Syndrome Society (NDSS)

- Mr. Frederick Isasi, J.D. MPH, Executive Director, Families USA
- Ms. Molly Cain, Parent Advocate
- Dr. Stephen Loyd, MD, Chief Medical Officer, Cedar Recovery
- Dr. Timothy Westlake, MD, Emergency Medicine Physician

COMMITTEE COST ESTIMATE

Pursuant to clause 3(d)(1) of rule XIII, the Committee adopts as its own the cost estimate prepared by the Director of the Congressional Budget Office pursuant to section 402 of the Congressional Budget Act of 1974. At the time this report was filed, the estimate was not available.

EARMARK, LIMITED TAX BENEFITS, AND LIMITED TARIFF BENEFITS

Pursuant to clause 9(e), 9(f), and 9(g) of rule XXI, the Committee finds that H.R. 467 contains no earmarks, limited tax benefits, or limited tariff benefits.

ADVISORY COMMITTEE STATEMENT

No advisory committees within the meaning of section 5(b) of the Federal Advisory Committee Act were created by this legislation.

APPLICABILITY TO LEGISLATIVE BRANCH

The Committee finds that the legislation does not relate to the terms and conditions of employment or access to public services or accommodations within the meaning of section 102(b)(3) of the Congressional Accountability Act.

SECTION-BY-SECTION ANALYSIS OF THE LEGISLATION

Section 1. Short title

Section 1 provides a short title of "Halt All Lethal Trafficking of Fentanyl Act" or the "HALT Fentanyl Act".

Section 2. Class scheduling of fentanyl-related substances

Section 2 amends 202(c) of the CSA to place FRS into schedule 1 permanently.

Section 3. Registration requirements related to research

Section 3 establishes a new, alternative registration process for schedule 1 research that is federally funded. It also makes several changes to registration requirements for conducting research, including permitting a single registration for related research sites in certain circumstances, waiving the requirement for a new inspection in certain situations, and allowing a registered researcher to perform certain manufacturing activities with small quantities of a substance without obtaining a manufacturing registration.

Section 4. Rulemaking

Section 4 requires DEA to issue a final rule to implement this Act.

Section 5. Penalties

Section 5 clarifies that fentanyl related substances shall be subject to the same penalties as fentanyl analogues when permanently placed in schedule 1.

Section 6. Applicability, other matters

Includes a Sense of Congress that indicates Congress agrees with the interpretation of the CSA in *United States vs. McCray*.

CHANGES IN EXISTING LAW MADE BY THE BILL, AS REPORTED

In compliance with clause 3(e) of rule XIII of the Rules of the House of Representatives, changes in existing law made by the bill, as reported, are shown as follows (existing law proposed to be omitted is enclosed in black brackets, new matter is printed in italics, and existing law in which no change is proposed is shown in roman):

CONTROLLED SUBSTANCES ACT

TITLE II—CONTROL AND ENFORCEMENT

* * * * * * *

PART B—AUTHORITY TO CONTROL; STANDARDS AND SCHEDULES

* * * * * * *

SCHEDULES OF CONTROLLED SUBSTANCES

SEC. 202. (a) There are established five schedules of controlled substances, to be known as schedules I, II, III, IV, and V. Such schedules shall initially consist of the substances listed in this section. The schedules established by this section shall be updated and republished on a semiannual basis during the two-year period beginning one year after the date of enactment of this title and shall be updated and republished on an annual basis thereafter.

(b) Except where control is required by United States obligations under an international treaty, convention, or protocol, in effect on the effective date of this part, and except in the case of an immediate precursor, a drug or other substance may not be placed in any schedule unless the findings required for such schedule are made with respect to such drug or other substance. The findings required for each of the schedules are as follows:

(1) SCHEDULE I.—

(A) The drug or other substance has a high potential for abuse.

(B) The drug or other substance has no currently accepted medical use in treatment in the United States.

(C) There is a lack of accepted safety for use of the drug or other substance under medical supervision.

(2) SCHEDULE II.—

(A) The drug or other substance has a high potential for abuse.

(B) The drug or other substance has a currently accepted medical use in treatment in the United States or a currently accepted medical use with severe restrictions.

(C) Abuse of the drug or other substances may lead to severe psychological or physical dependence.

(3) SCHEDULE III.—

(A) The drug or other substance has a potential for abuse less than the drugs or other substances in schedules I and II.

(B) The drug or other substance has a currently accepted medical use in treatment in the United States.

(C) Abuse of the drug or other substance may lead to moderate or low physical dependence or high psychological dependence.

(4) SCHEDULE IV.—

(A) The drug or other substance has a low potential for abuse relative to the drugs or other substances in schedule III.

(B) The drug or other substance has a currently accepted medical use in treatment in the United States.

(C) Abuse of the drug or other substance may lead to limited physical dependence or psychological dependence relative to the drugs or other substances in schedule III.

(5) SCHEDULE V.—

(A) The drug or other substance has a low potential for abuse relative to the drugs or other substances in schedule IV.

(B) The drug or other substance has a currently accepted medical use in treatment in the United States.

(C) Abuse of the drug or other substance may lead to limited physical dependence or psychological dependence relative to the drugs or other substances in schedule IV.

(c) Schedules I, II, III, IV, and V shall, unless and until amended pursuant to section 201, consist of the following drugs or other substances, by whatever official name, common or usual name, chemical name, or brand name designated:

SCHEDULE I

(a) Unless specifically excepted or unless listed in another schedule, any of the following opiates, including their isomers, esters, ethers, salts, and salts of isomers, esters, and ethers, whenever the existence of such isomers, esters, ethers, and salts is possible within the specific chemical designation:

(1) Acetylmethadol.
(2) Allylprodine.
(3) Alphacetylmathadol.[26]
(4) Alphameprodine.
(5) Alphamethadol.
(6) Benzethidine.
(7) Betacetylmethadol.
(8) Betameprodine.
(9) Betamethadol.
(10) Betaprodine.
(11) Clonitazene.
(12) Dextromoramide.
(13) Dextrorphan.
(14) Diampromide.
(15) Diethylthiambutene.
(16) Dimenoxadol.

[26] So in law. Probably should be "Alphacetylmethadol."

(17) Dimepheptanol.
(18) Dimethylthiambutene.
(19) Dioxaphetyl butyrate.
(20) Dipipanone.
(21) Ethylmethylthiambutene.
(22) Etonitazene.
(23) Etoxeridine.
(24) Furethidine.
(25) Hydroxypethidine.
(26) Ketobemidone.
(27) Levomoramide.
(28) Levophenacylmorphan.
(29) Morpheridine.
(30) Noracymethadol.
(31) Norlevorphanol.
(32) Normethadone.
(33) Norpipanone.
(34) Phenadoxone.
(35) Phenampromide.
(36) Phenomorphan.
(37) Phenoperidine.
(38) Piritramide.
(39) Proheptazine.
(40) Properidine.
(41) Racemoramide.
(42) Trimeperidine.

(b) Unless specifically excepted or unless listed in another schedule, any of the following opium derivatives, 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:

(1) Acetorphine.
(2) Acetyldihydrocodeine.
(3) Benzylmorphine.
(4) Codeine methylbromide.
(5) Codeine-N-Oxide.
(6) Cyprenorphine.
(7) Desomorphine.
(8) Dihydromorphine.
(9) Etorphine.
(10) Heroin.
(11) Hydromorphinol.
(12) Methyldesorphine.
(13) Methylhydromorphine.
(14) Morphine methylbromide.
(15) Morphine methylsulfonate.
(16) Morphine-N-Oxide.
(17) Myrophine.
(18) Nicocodeine.
(19) Nicomorphine.
(20) Normorphine.
(21) Pholcodine.
(22) Thebacon.

(c) Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation, which con-

tains any quantity of the following hallucinogenic substances, or which contains any of 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:

(1) 3,4-methylenedioxy amphetamine.
(2) 5-methoxy-3,4-methylenedioxy amphetamine.
(3) 3,4,5-trimethoxy amphetamine.
(4) Bufotenine.
(5) Diethyltryptamine.
(6) Dimethyltryptamine.
(7) 4-methyl-2,5-dimethoxy amphetamine.
(8) Ibogaine.
(9) Lysergic acid diethylamide.
(10) Marihuana.
(11) Mescaline.
(12) Peyote.
(13) N-ethyl-3-piperidyl benzilate.
(14) N-methyl-3-piperidyl benzilate.
(15) Psilocybin.
(16) Psilocyn.
(17) Tetrahydrocannabinols, except for tetrahydrocannabinols in hemp (as defined under section 297A of the Agricultural Marketing Act of 1946).
(18) 4-methylmethcathinone (Mephedrone).
(19) 3,4-methylenedioxypyrovalerone (MDPV).
(20) 2-(2,5-Dimethoxy-4-ethylphenyl)ethanamine (2C–E).
(21) 2-(2,5-Dimethoxy-4-methylphenyl)ethanamine (2C–D).
(22) 2-(4-Chloro-2,5-dimethoxyphenyl)ethanamine (2C–C).
(23) 2-(4-Iodo-2,5-dimethoxyphenyl)ethanamine (2C–I).
(24) 2-[4-(Ethylthio)-2,5-dimethoxyphenyl]ethanamine (2C–T–2).
(25) 2-[4-(Isopropylthio)-2,5-dimethoxyphenyl]ethanamine (2C–T–4).
(26) 2-(2,5-Dimethoxyphenyl)ethanamine (2C–H).
(27) 2-(2,5-Dimethoxy-4-nitro-phenyl)ethanamine (2C–N).
(28) 2-(2,5-Dimethoxy-4-(n)-propylphenyl)ethanamine (2C–P).

(d)(1) Unless specifically exempted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of cannabimimetic agents, 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):

(A) The term "cannabimimetic agents" means any substance that is a cannabinoid receptor type 1 (CB1 receptor) agonist as demonstrated by binding studies and functional assays within any of the following structural classes:

(i) 2-(3-hydroxycyclohexyl)phenol with substitution at the 5-position of the phenolic ring by alkyl or alkenyl, whether or not substituted on the cyclohexyl ring to any extent.

(ii) 3-(1-naphthoyl)indole or 3-(1-naphthylmethane)indole by substitution at the nitrogen atom of the indole ring, whether or not further substituted on the indole ring to

any extent, whether or not substituted on the naphthoyl or naphthyl ring to any extent.

(iii) 3-(1-naphthoyl)pyrrole by substitution at the nitrogen atom of the pyrrole ring, whether or not further substituted in the pyrrole ring to any extent, whether or not substituted on the naphthoyl ring to any extent.

(iv) 1-(1-naphthylmethylene)indene by substitution of the 3-position of the indene ring, whether or not further substituted in the indene ring to any extent, whether or not substituted on the naphthyl ring to any extent.

(v) 3-phenylacetylindole or 3-benzoylindole by substitution at the nitrogen atom of the indole ring, whether or not further substituted in the indole ring to any extent, whether or not substituted on the phenyl ring to any extent.

(B) Such term includes—

(i) 5-(1,1-dimethylheptyl)-2-[(1R,3S)-3-hydroxycyclohexyl]-phenol (CP–47,497);

(ii) 5-(1,1-dimethyloctyl)-2-[(1R,3S)-3-hydroxycyclohexyl]-phenol (cannabicyclohexanol or CP–47,497 C8-homolog);

(iii) 1-pentyl-3-(1-naphthoyl)indole (JWH–018 and AM678);

(iv) 1-butyl-3-(1-naphthoyl)indole (JWH–073);

(v) 1-hexyl-3-(1-naphthoyl)indole (JWH–019);

(vi) 1-[2-(4-morpholinyl)ethyl]-3-(1-naphthoyl)indole (JWH–200);

(vii) 1-pentyl-3-(2-methoxyphenylacetyl)indole (JWH–250);

(viii) 1-pentyl-3-[1-(4-methoxynaphthoyl)]indole (JWH–081);

(ix) 1-pentyl-3-(4-methyl-1-naphthoyl)indole (JWH–122);

(x) 1-pentyl-3-(4-chloro-1-naphthoyl)indole (JWH–398);

(xi) 1-(5-fluoropentyl)-3-(1-naphthoyl)indole (AM2201);

(xii) 1-(5-fluoropentyl)-3-(2-iodobenzoyl)indole (AM694);

(xiii) 1-pentyl-3-[(4-methoxy)-benzoyl]indole (SR–19 and RCS–4);

(xiv) 1-cyclohexylethyl-3-(2-methoxyphenylacetyl)indole (SR–18 and RCS–8); and

(xv) 1-pentyl-3-(2-chlorophenylacetyl)indole (JWH–203).

(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, alkoxyl, hydroxyl, halo, haloalkyl, amino, or nitro groups.

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

(D) By replacement of the aniline ring with any aromatic monocycle whether or not further substituted 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).

SCHEDULE II

(a) Unless specifically excepted or unless listed in another schedule, any of the following substances whether produced directly or indirectly by extraction from substances of vegetable origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis:

(1) Opium and opiate, and any salt, compound, derivative, or preparation of opium or opiate.

(2) Any salt, compound, derivative, or preparation thereof which is chemically equivalent or identical with any of the substances referred to in clause (1), except that these substances shall not include the isoquinoline alkaloids of opium.

(3) Opium poppy and poppy straw.

(4) coca[27] leaves, except coca leaves and extracts of coca leaves from which cocaine, ecgonine, and derivatives of ecgonine or their salts have been removed; cocaine, its salts, optical and geometric isomers, and salts of isomers; ecgonine, its derivatives, their salts, isomers, and salts of isomers; or any compound, mixture, or preparation which contains any quantity of any of the substances referred to in this paragraph.

(b) Unless specifically excepted or unless listed in another schedule, any of the following opiates, including their isomers, esters, ethers, salts, and salts of isomers, esters and ethers, whenever the existence of such isomers, esters, ethers, and salts is possible within the specific chemical designation:

(1) Alphaprodine.

(2) Anileridine.

(3) Bezitramide.

(4) Dihydrocodeine.

[27] So in law. Probably should be "Coca".

(5) Diphenoxylate.
(6) Fentanyl.
(7) Isomethadone.
(8) Levomethorphan.
(9) Levorphanol.
(10) Metazocine.
(11) Methadone.
(12) Methadone-Intermediate, 4-cyano-2-dimethylamino-4,4-diphenyl butane.
(13) Moramide-Intermediate, 2-methyl-3 morpholino-1,1-diphenylpropane-carboxylic acid.
(14) Pethidine.
(15) Pethidine-Intermediate-A, 4-cyano-1-methyl-4-phenylpiperidine.
(16) Pethidine-Intermediate-B, ethyl-4-phenylpiperidine-4-carboxylate.
(17) Pethidine-Intermediate-C, 1-methyl-4-phenylpiperidine-4-carboxylic acid.
(18) Phenazocine.
(19) Piminodine.
(20) Racemethorphan.
(21) Racemorphan.

(c) Unless specifically excepted or unless listed in another schedule, any injectable liquid which contains any quantity of methamphetamine, including its salts, isomers, and salts of isomers.

SCHEDULE III

(a)[28] Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a stimulant effect on the central nervous system:

(1) Amphetamine, its salts, optical isomers, and salts of its optical isomers.
(2) Phenmetrazine and its salts.
(3) Any substance (except an injectable liquid) which contains any quantity of methamphetamine, including its salts, isomers, and salts of isomers.
(4) Methylphenidate.

(b) Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a depressant effect on the central nervous system:

(1) Any substance which contains any quantity of a derivative of barbituric acid, or any salt of a derivative of barbituric acid.
(2) Chorexadol.
(3) Glutethimide.
(4) Lysergic acid.
(5) Lysergic acid amide.
(6) Methyprylon.
(7) Phencyclidine.
(8) Sulfondiethylmethane.

[28] The substances referred to in schedule III(a) have been administratively moved to schedule II.

(9) Sulfonethylmethane.
(10) Sulfonmethane.

(c) Nalorphine.

(d) Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation containing limited quantities of any of the following narcotic drugs, or any salts thereof:

(1) Not more than 1.8 grams of codeine per 100 milliliters or not more than 90 milligrams per dosage unit, with an equal or greater quantity of an isoquinoline alkaloid of opium.

(2) Not more than 1.8 grams of codeine per 100 milliliters or not more than 90 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts.

(3) Not more than 300 milligrams of dihydrocodeinone per 100 milliliters or not more than 15 milligrams per dosage unit, with a fourfold or greater quantity of an isoquinoline alkaloid of opium.

(4) Not more than 300 milligrams of dihydrocodeinone per 100 milliliters or not more than 15 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts.

(5) Not more than 1.8 grams of dihydrocodeine per 100 milliliters or not more than 90 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts.

(6) Not more than 300 milligrams of ethylmorphine per 100 milliliters or not more than 15 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts.

(7) Not more than 500 milligrams of opium per 100 milliliters or per 100 grams, or not more than 25 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts.

(8) Not more than 50 milligrams of morphine per 100 milliliters or per 100 grams with one or more active, nonnarcotic ingredients in recognized therapeutic amounts.

(e) Anabolic steroids.

SCHEDULE IV

(1) Barbital.
(2) Chloral betaine.
(3) Chloral hydrate.
(4) Ethchlorvynol.
(5) Ethinamate.
(6) Methohexital.
(7) Meprobamate.
(8) Methylphenobarbital.
(9) Paraldehyde.
(10) Petrichloral.
(11) Phenobarbital.

SCHEDULE V

Any compound, mixture, or preparation containing any of the following limited quantities of narcotic drugs, which shall include one or more nonnarcotic active medicinal ingredients in sufficient proportion to confer upon the compound, mixture, or preparation valuable medicinal qualities other than those possessed by the narcotic drug alone:

(1) Not more than 200 milligrams of codeine per 100 milliliters or per 100 grams.

(2) Not more than 100 milligrams of dihydrocodeine per 100 milliliters or per 100 grams.

(3) Not more than 100 milligrams of ethylmorphine per 100 milliliters or per 100 grams.

(4) Not more than 2.5 milligrams of diphenoxylate and not less than 25 micrograms of atropine sulfate per dosage unit.

(5) Not more than 100 milligrams of opium per 100 milliliters or per 100 grams.

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PART C—REGISTRATION OF MANUFACTURERS, DISTRIBUTORS, AND DISPENSERS OF CONTROLLED SUBSTANCES; PIPERIDINE REPORTING

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PERSONS REQUIRED TO REGISTER

SEC. 302. (a)(1) Every person who manufactures or distributes any controlled substance or list I chemical, or who proposes to engage in the manufacture or distribution of any controlled substance or list I chemical, shall obtain annually a registration issued by the Attorney General in accordance with the rules and regulations promulgated by him.

(2) Every person who dispenses, or who proposes to dispense, any controlled substance, shall obtain from the Attorney General a registration issued in accordance with the rules and regulations promulgated by him. The Attorney General shall, by regulation, determine the period of such registrations. In no event; however, shall such registrations be issued for less than one year nor for more than three years.

(3)(A) Except as provided in subparagraph (C), the registration of any registrant under this title to manufacture, distribute, or dispense controlled substances or list I chemicals terminates if and when such registrant—

(i) dies;

(ii) ceases legal existence;

(iii) discontinues business or professional practice; or

(iv) surrenders such registration.

(B) In the case of such a registrant who ceases legal existence or discontinues business or professional practice, such registrant shall promptly notify the Attorney General in writing of such fact.

(C) No registration under this title to manufacture, distribute, or dispense controlled substances or list I chemicals, and no authority conferred thereby, may be assigned or otherwise transferred except upon such conditions as the Attorney General may specify and then only pursuant to written consent. A registrant to whom a registra-

tion is assigned or transferred pursuant to the preceding sentence may not manufacture, distribute, or dispense controlled substances or list I chemicals pursuant to such registration until the Attorney General receives such written consent.

(D) In the case of a registrant under this title to manufacture, distribute, or dispense controlled substances or list I chemicals desiring to discontinue business or professional practice altogether or with respect to controlled substances and list I chemicals (without assigning or transferring such business or professional practice to another entity), such registrant shall return to the Attorney General for cancellation—

(i) the registrant's certificate of registration;

(ii) any unexecuted order forms in the registrant's possession; and

(iii) any other documentation that the Attorney General may require.

(b) Persons registered by the Attorney General under this title to manufacture, distribute, or dispense controlled substances or list I chemicals are authorized to possess, manufacture, distribute, or dispense such substances or chemicals (including any such activity in the conduct of research) to the extent authorized by their registration and in conformity with the other provisions of this title.

(c) The following persons shall not be required to register and may lawfully possess any controlled substance or list I chemical under this title:

(1) An agent or employee of any registered manufacturer, distributor, or dispenser of any controlled substance or list I chemical if such agent or employee is acting in the usual course of his business or employment.

(2) A common or contract carrier or warehouseman, or an employee thereof, whose possession of the controlled substance or list I chemical is in the usual course of his business or employment.

(3) An ultimate user who possesses such substance for a purpose specified in section 102(25).

(4) An agent or employee of a research institution 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 possess the substance without a separate registration.

(d) The Attorney General may, by regulation, waive the requirement for registration of certain manufacturers, distributors, or dispensers if he finds it consistent with the public health and safety.

(e)(1) A separate registration shall be required at each principal place of business or professional practice where the applicant manufactures, distributes, or dispenses controlled substances or list I chemicals.

(2) Notwithstanding paragraph (1), a registrant who is a veterinarian shall not be required to have a separate registration in order to transport and dispense controlled substances in the usual course of veterinary practice at a site other than the registrant's registered principal place of business or professional practice, so long as the site of transporting and dispensing is located in a State where the veterinarian is licensed to practice veterinary medicine and is not a principal place of business or professional practice.

(3) Notwithstanding paragraph (1), a registrant that is dispensing pursuant to section 303(g) narcotic drugs to individuals for maintenance treatment or detoxification treatment shall not be required to have a separate registration to incorporate one or more mobile medication units into the registrant's practice to dispense such narcotics at locations other than the registrant's principal place of business or professional practice described in paragraph (1), so long as the registrant meets such standards for operation of a mobile medication unit as the Attorney General may establish.

(4)(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 substances at the research sites;

(iii) the maintenance of records for the research sites; and

(iv) any other matters necessary to ensure effective controls against diversion at the research sites.

[(f) The] *(f) (1) The* Attorney General is authorized to inspect the establishment of a registrant or applicant for registration in accordance with the rules and regulations promulgated by him.

(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 schedule 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.

(g)(1) An ultimate user who has lawfully obtained a controlled substance in accordance with this title may, without being registered, deliver the controlled substance to another person for the purpose of disposal of the controlled substance if—

(A) the person receiving the controlled substance is authorized under this title to engage in such activity; and

(B) the disposal takes place in accordance with regulations issued by the Attorney General to prevent diversion of controlled substances.

(2) In developing regulations under this subsection, the Attorney General shall take into consideration the public health and safety, as well as the ease and cost of program implementation and participation by various communities. Such regulations may not require any entity to establish or operate a delivery or disposal program.

(3) The Attorney General may, by regulation, authorize long-term care facilities, as defined by the Attorney General by regulation, to dispose of controlled substances on behalf of ultimate users who reside, or have resided, at such long-term care facilities in a manner that the Attorney General determines will provide effective controls against diversion and be consistent with the public health and safety.

(4) If a person dies while lawfully in possession of a controlled substance for personal use, any person lawfully entitled to dispose of the decedent's property may deliver the controlled substance to another person for the purpose of disposal under the same conditions as provided in paragraph (1) for an ultimate user.

(5)(A) In the case of a person receiving hospice care, an employee of a qualified hospice program, acting within the scope of employment, may handle, without being registered under this section, any controlled substance that was lawfully dispensed to the person receiving hospice care, for the purpose of disposal of the controlled substance so long as such disposal occurs onsite in accordance with all applicable Federal, State, Tribal, and local law and—

(i) the disposal occurs after the death of a person receiving hospice care;

(ii) the controlled substance is expired; or

(iii)(I) the employee is—

(aa) the physician of the person receiving hospice care; and

(bb) registered under section 303(g); and

(II) the hospice patient no longer requires the controlled substance because the plan of care of the hospice patient has been modified.

(B) For the purposes of this paragraph:

(i) The terms "hospice care" and "hospice program" have the meanings given to those terms in section 1861(dd) of the Social Security Act.

(ii) The term "employee of a qualified hospice program" means a physician, physician assistant, nurse, or other person who—

(I) is employed by, or pursuant to arrangements made by, a qualified hospice program;

(II)(aa) is licensed to perform medical or nursing services by the jurisdiction in which the person receiving hospice care was located; and

(bb) is acting within the scope of such employment in accordance with applicable State law; and

(III) has completed training through the qualified hospice program regarding the disposal of controlled substances in a secure and responsible manner so as to discourage abuse, misuse, or diversion.

(iii) The term "qualified hospice program" means a hospice program that—

(I) has written policies and procedures for assisting in the disposal of the controlled substances of a person receiving hospice care after the person's death;

(II) at the time when the controlled substances are first ordered—

(aa) provides a copy of the written policies and procedures to the patient or patient representative and family;

(bb) discusses the policies and procedures with the patient or representative and the family in a language and manner that they understand to ensure that these parties are educated regarding the safe disposal of controlled substances; and

(cc) documents in the patient's clinical record that the written policies and procedures were provided and discussed; and

(III) at the time following the disposal of the controlled substances—

(aa) documents in the patient's clinical record the type of controlled substance, dosage, route of administration, and quantity so disposed; and

(bb) the time, date, and manner in which that disposal occurred.

(h) CONTINUATION OF RESEARCH ON SUBSTANCES NEWLY ADDED TO SCHEDULE I.—If a person is conducting 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 schedule 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 research on the substance, in accordance with regulations issued by the Attorney General for purposes of this paragraph;

(2) the person may, notwithstanding subsections (a) and (b), continue to conduct the research 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 hearing may be held at a later time if so requested by the person; and

(4) if the person sends a copy of the application described in paragraph (1) to a manufacturer or distributor of the substance, receipt of the copy by the manufacturer or distributor shall constitute sufficient evidence that the person is authorized to receive the substance.

(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.

REGISTRATION REQUIREMENTS

SEC. 303. (a) The Attorney General shall register an applicant to manufacture controlled substances in schedule I or II if he determines that such registration is consistent with the public interest and with United States obligations under international treaties, conventions, or protocols in effect on the effective date of this part. In determining the public interest, the following factors shall be considered:

(1) maintenance of effective controls against diversion of particular controlled substances and any controlled substance in schedule I or II compounded therefrom into other than legitimate medical, scientific, research, or industrial channels, by limiting the importation and bulk manufacture of such controlled substances to a number of establishments which can produce an adequate and uninterrupted supply of these substances under adequately competitive conditions for legitimate medical, scientific, research, and industrial purposes;

(2) compliance with applicable State and local law;

(3) promotion of technical advances in the art of manufacturing these substances and the development of new substances;

(4) prior conviction record of applicant under Federal and State laws relating to the manufacture, distribution, or dispensing of such substances;

(5) past experience in the manufacture of controlled substances, and the existence in the establishment of effective control against diversion; and

(6) such other factors as may be relevant to and consistent with the public health and safety.

(b) The Attorney General shall register an applicant to distribute a controlled substance in schedule I or II unless he determines that the issuance of such registration is inconsistent with the public interest. In determining the public interest, the following factors shall be considered:

(1) maintenance of effective controls against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels;

(2) compliance with applicable State and local law;

(3) prior conviction record of applicant under Federal or State laws relating to the manufacture, distribution, or dispensing of such substances;

(4) past experience in the distribution of controlled substances; and

(5) such other factors as may be relevant to and consistent with the public health and safety.

(c)(1)(A) As it relates to applications to manufacture marijuana for research purposes, when the Attorney General places a notice in the Federal Register to increase the number of entities registered under this Act to manufacture marijuana to supply appropriately registered researchers in the United States, the Attorney General shall, not later than 60 days after the date on which the Attorney General receives a completed application—

(i) approve the application; or

(ii) request supplemental information.

(B) For purposes of subparagraph (A), an application shall be deemed complete when the applicant has submitted documentation showing each of the following:

(i) The requirements designated in the notice in the Federal Register are satisfied.

(ii) The requirements under this Act are satisfied.

(iii) The applicant will limit the transfer and sale of any marijuana manufactured under this subsection—

(I) to researchers who are registered under this Act to conduct research with controlled substances in schedule I; and

(II) for purposes of use in preclinical research or in a clinical investigation pursuant to an investigational new drug exemption under 505(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(i)).

(iv) The applicant will transfer or sell any marijuana manufactured under this subsection only with prior, written consent for the transfer or sale by the Attorney General.

(v) The applicant has completed the application and review process under subsection (a) for the bulk manufacture of controlled substances in schedule I.

(vi) The applicant has established and begun operation of a process for storage and handling of controlled substances in schedule I, including for inventory control and monitoring security in accordance with section 105 of the Medical Marijuana and Cannabidiol Research Expansion Act.

(vii) The applicant is licensed by each State in which the applicant will conduct operations under this subsection, to manufacture marijuana, if that State requires such a license.

(C) Not later than 30 days after the date on which the Attorney General receives supplemental information requested under subparagraph (A)(ii) with respect to an application, the Attorney General shall approve or deny the application.

(2) If an application described in this subsection is denied, the Attorney General shall provide a written explanation of the basis of denial to the applicant.

(d) Registration granted under subsections (a) and (b) of this section shall not entitle a registrant to (1) manufacture or distribute controlled substances in schedule I or II other than those specified in the registration, or (2) manufacture any quantity of those controlled substances in excess of the quota assigned pursuant to section 306.

(e) The Attorney General shall register an applicant to manufacture controlled substances in schedule III, IV, or V, unless he determines that the issuance of such registration is inconsistent with

the public interest. In determining the public interest, the following factors shall be considered:

(1) maintenance of effective controls against diversion of particular controlled substances and any controlled substance in schedule III, IV, or V compounded therefrom into other than legitimate medical, scientific, or industrial channels;

(2) compliance with applicable State and local law;

(3) promotion of technical advances in the art of manufacturing these substances and the development of new substances;

(4) prior conviction record of applicant under Federal or State laws relating to the manufacture, distribution, or dispensing of such substances;

(5) past experience in the manufacture, distribution, and dispensing of controlled substances, and the existence in the establishment of effective controls against diversion; and

(6) such other factors as may be relevant to and consistent with the public health and safety.

(f) The Attorney General shall register an applicant to distribute controlled substances in schedule III, IV, or V, unless he determines that the issuance of such registration is inconsistent with the public interest. In determining the public interest, the following factors shall be considered:

(1) maintenance of effective controls against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels;

(2) compliance with applicable State and local law;

(3) prior conviction record of applicant under Federal or State laws relating to the manufacture, distribution, or dispensing of such substances;

(4) past experience in the distribution of controlled substances; and

(5) such other factors as may be relevant to and consistent with the public health and safety.

(g)(1) The Attorney General shall register practitioners (including pharmacies, as distinguished from pharmacists) to dispense, or conduct research with, controlled substances in schedule II, III, IV, or V and shall modify the registrations of pharmacies so registered to authorize them to dispense controlled substances by means of the Internet, if the applicant is authorized to dispense, or conduct research with respect to, controlled substances under the laws of the State in which he practices. The Attorney General may deny an application for such registration or such modification of registration if the Attorney General determines that the issuance of such registration or modification would be inconsistent with the public interest. In determining the public interest, the following factors shall be considered:

(A) The recommendation of the appropriate State licensing board or professional disciplinary authority.

(B) The applicant's experience in dispensing, or conducting research with respect to controlled substances.

(C) The applicant's conviction record under Federal or State laws relating to the manufacture, distribution, or dispensing of controlled substances.

(D) Compliance with applicable State, Federal, or local laws relating to controlled substances.

(E) Such other conduct which may threaten the public health and safety.

Separate registration under this part for practitioners engaging in research with controlled substances in schedule II, III, IV, or V, who are already registered under this part in another capacity, shall not be required.

(2) (A) Registration applications by practitioners wishing to conduct research with controlled substances in schedule I shall be referred to the Secretary, who shall determine the qualifications and competency of each practitioner requesting registration, as well as the merits of the research protocol. The Secretary, in determining the merits of each research protocol, shall consult with the Attorney General as to effective procedures to adequately safeguard against diversion of such controlled substances from legitimate medical or scientific use. Registration for the purpose of bona fide research with controlled substances in schedule I by a practitioner deemed qualified by the Secretary may be denied by the Attorney General only on a ground specified in section 304(a).

(B)(i) The Attorney General shall register a practitioner to conduct research with marijuana (including any derivative, extract, preparation, and compound thereof) if—

(I) the applicant's research protocol has been reviewed and allowed—

(aa) by the Secretary of Health and Human Services under section 505(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(i));

(bb) by the National Institutes of Health or another Federal agency that funds scientific research; or

(cc) pursuant to sections 1301.18 and 1301.32 of title 21, Code of Federal Regulations, or any successors thereto; and

(II) the applicant has demonstrated to the Attorney General that there are effective procedures in place to adequately safeguard against diversion of the controlled substance for legitimate medical or scientific use pursuant to section 105 of the Medical Marijuana and Cannabidiol Research Expansion Act, including demonstrating that the security measures are adequate for storing the quantity of marijuana the applicant would be authorized to possess.

(ii) The Attorney General may deny an application for registration under this subparagraph only if the Attorney General determines that the issuance of the registration would be inconsistent with the public interest. In determining the public interest, the Attorney General shall consider the factors listed in—

(I) subparagraphs (B) through (E) of paragraph (1); and

(II) subparagraph (A) of paragraph (1), if the applicable State requires practitioners conducting research to register with a board or authority described in such subparagraph (A).

(iii)(I) Not later than 60 days after the date on which the Attorney General receives a complete application for registration under this subparagraph, the Attorney General shall—

(aa) approve the application; or

(bb) request supplemental information.

(II) For purposes of subclause (I), an application shall be deemed complete when the applicant has submitted documentation showing that the requirements under clause (i) are satisfied.

(iv) Not later than 30 days after the date on which the Attorney General receives supplemental information as described in clause (iii)(I)(bb) in connection with an application described in this subparagraph, the Attorney General shall approve or deny the application.

(v) If an application described in this subparagraph is denied, the Attorney General shall provide a written explanation of the basis of denial to the applicant.

(vi)(I) If the Attorney General grants an application for registration under clause (i), the registrant may amend or supplement the research protocol without notification to, or review by, the Drug Enforcement Administration if the registrant does not change—

(aa) the quantity or type of marijuana or cannabidiol (including any derivative, extract, preparation, and compound thereof);

(bb) the source of such marijuana or cannabidiol; or

(cc) the conditions under which such marijuana or cannabidiol is stored, tracked, or administered.

(II)(aa) If a registrant under clause (i) seeks to change the type of marijuana or cannabidiol (including any derivative, extract, preparation, and compound thereof), the source of such marijuana or cannabidiol, or the conditions under which such marijuana or cannabidiol is stored, tracked, or administered, the registrant shall notify the Attorney General via registered mail, or an electronic means permitted by the Attorney General, not later than 30 days before implementing an amended or supplemental research protocol.

(bb) A registrant may proceed with an amended or supplemental research protocol described in item (aa) if the Attorney General does not explicitly object during the 30-day period beginning on the date on which the Attorney General receives the notice under item (aa).

(cc) The Attorney General may only object to an amended or supplemental research protocol under this subclause if additional security measures are needed to safeguard against diversion or abuse.

(dd) If a registrant under clause (i) seeks to address additional security measures identified by the Attorney General under item (cc), the registrant shall notify the Attorney General via registered mail, or an electronic means permitted by the Attorney General, not later than 30 days before implementing an amended or supplemental research protocol.

(ee) A registrant may proceed with an amended or supplemental research protocol described in item (dd) if the Attorney General does not explicitly object during the 30-day period beginning on the date on which the Attorney General receives the notice under item (dd).

(III)(aa) If a registrant under clause (i) seeks to change the quantity of marijuana needed for research and the change in quantity does not impact the factors described in item (bb) or (cc) of subclause (I) of this clause, the registrant shall notify the Attorney General via registered mail or using an electronic means permitted by the Attorney General.

(bb) A notification under item (aa) shall include—

(AA) the Drug Enforcement Administration registration number of the registrant;

(BB) the quantity of marijuana or cannabidiol already obtained;

(CC) the quantity of additional marijuana or cannabidiol needed to complete the research; and

(DD) an attestation that the change in quantity does not impact the source of the marijuana or cannabidiol or the conditions under which the marijuana or cannabidiol is stored, tracked, or administered.

(cc) The Attorney General shall ensure that—

(AA) any registered mail return receipt with respect to a notification under item (aa) is submitted for delivery to the registrant providing the notification not later than 3 days after receipt of the notification by the Attorney General; and

(BB) notice of receipt of a notification using an electronic means permitted under item (aa) is provided to the registrant providing the notification not later than 3 days after receipt of the notification by the Attorney General.

(dd)(AA) On and after the date described in subitem (BB), a registrant that submits a notification in accordance with item (aa) may proceed with the research as if the change in quantity has been approved on such date, unless the Attorney General notifies the registrant of an objection described in item (ee).

(BB) The date described in this subitem is the date on which a registrant submitting a notification under item (aa) receives the registered mail return receipt with respect to the notification or the date on which the registrant receives notice that the notification using an electronic means permitted under item (aa) was received by the Attorney General, as the case may be.

(ee) A notification submitted under item (aa) shall be deemed to be approved unless the Attorney General, not later than 10 days after receiving the notification, explicitly objects based on a finding that the change in quantity—

(AA) does impact the source of the marijuana or cannabidiol or the conditions under which the marijuana or cannabidiol is stored, tracked, or administered; or

(BB) necessitates that the registrant implement additional security measures to safeguard against diversion or abuse.

(IV) Nothing in this clause shall limit the authority of the Secretary of Health and Human Services over requirements related to research protocols, including changes in—

(aa) the method of administration of marijuana or cannabidiol;

(bb) the dosing of marijuana or cannabidiol; and

(cc) the number of individuals or patients involved in research.

(3) Article 7 of the Convention on Psychotrophic Substances shall not be construed to prohibit, or impose additional restrictions upon, research involving drugs or other substances scheduled under the convention which is conducted in conformity with this subsection and other applicable provisions of this title.

(h)(1) Except as provided in paragraph (2), practitioners who dispense narcotic drugs to individuals for maintenance treatment or

detoxification treatment shall obtain annually a separate registration for that purpose. The Attorney General shall register an applicant to dispense narcotic drugs to individuals for maintenance treatment or detoxification treatment (or both)—

(A) if the applicant is a practitioner who is determined by the Secretary to be qualified (under standards established by the Secretary) to engage in the treatment with respect to which registration is sought;

(B) if the Attorney General determines that the applicant will comply with standards established by the Attorney General respecting (i) security of stocks of narcotic drugs for such treatment, and (ii) the maintenance of records (in accordance with section 307) on such drugs; and

(C) if the Secretary determines that the applicant will comply with standards established by the Secretary (after consultation with the Attorney General) respecting the quantities of narcotic drugs which may be provided for unsupervised use by individuals in such treatment.

(2)(A) Subject to subparagraphs (D) and (J), the requirements of paragraph (1) are waived in the case of the dispensing (including the prescribing), by a practitioner, of narcotic drugs in schedule III, IV, or V or combinations of such drugs if the practitioner meets the conditions specified in subparagraph (B) and the narcotic drugs or combinations of such drugs meet the conditions specified in subparagraph (C).

(B) For purposes of subparagraph (A), the conditions specified in this subparagraph with respect to a practitioner are that, before the initial dispensing of narcotic drugs in schedule III, IV, or V or combinations of such drugs to patients for maintenance or detoxification treatment, the practitioner submit to the Secretary a notification of the intent of the practitioner to begin dispensing the drugs or combinations for such purpose, and that the notification contain the following certifications by the practitioner:

(i) The practitioner is a qualifying practitioner (as defined in subparagraph (G)).

(ii) With respect to patients to whom the practitioner will provide such drugs or combinations of drugs, the practitioner has the capacity to provide directly, by referral, or in such other manner as determined by the Secretary—

(I) all drugs approved by the Food and Drug Administration for the treatment of opioid use disorder, including for maintenance, detoxification, overdose reversal, and relapse prevention; and

(II) appropriate counseling and other appropriate ancillary services.

(iii)(I) The total number of such patients of the practitioner at any one time will not exceed the applicable number. Except as provided in subclause (II), the applicable number is 30.

(II) The applicable number is—

(aa) 100 if, not sooner than 1 year after the date on which the practitioner submitted the initial notification, the practitioner submits a second notification to the Secretary of the need and intent of the practitioner to treat up to 100 patients;

(bb) 100 if the practitioner holds additional credentialing, as defined in section 8.2 of title 42, Code of Federal Regulations (or successor regulations);

(cc) 100 if the practitioner provides medication-assisted treatment (MAT) using covered medications (as such terms are defined in section 8.2 of title 42, Code of Federal Regulations (or successor regulations)) in a qualified practice setting (as described in section 8.615 of title 42, Code of Federal Regulations (or successor regulations)); or

(dd) 275 if the practitioner meets the requirements specified in sections 8.610 through 8.655 of title 42, Code of Federal Regulations (or successor regulations).

(III) The Secretary may by regulation change such applicable number.

(IV) The Secretary may exclude from the applicable number patients to whom such drugs or combinations of drugs are directly administered by the qualifying practitioner in the office setting.

(C) For purposes of subparagraph (A), the conditions specified in this subparagraph with respect to narcotic drugs in schedule III, IV, or V or combinations of such drugs are as follows:

(i) The drugs or combinations of drugs have, under the Federal Food, Drug, and Cosmetic Act or section 351 of the Public Health Service Act, been approved for use in maintenance or detoxification treatment.

(ii) The drugs or combinations of drugs have not been the subject of an adverse determination. For purposes of this clause, an adverse determination is a determination published in the Federal Register and made by the Secretary, after consultation with the Attorney General, that the use of the drugs or combinations of drugs for maintenance or detoxification treatment requires additional standards respecting the qualifications of practitioners to provide such treatment, or requires standards respecting the quantities of the drugs that may be provided for unsupervised use.

(D)(i) A waiver under subparagraph (A) with respect to a practitioner is not in effect unless (in addition to conditions under subparagraphs (B) and (C)) the following conditions are met:

(I) The notification under subparagraph (B) is in writing and states the name of the practitioner.

(II) The notification identifies the registration issued for the practitioner pursuant to subsection (g).

(III) If the practitioner is a member of a group practice, the notification states the names of the other practitioners in the practice and identifies the registrations issued for the other practitioners pursuant to subsection (g).

(ii) Upon receiving a determination from the Secretary under clause (iii) finding that a practitioner meets all requirements for a waiver under subparagraph (B), the Attorney General shall assign the practitioner involved an identification number under this paragraph for inclusion with the registration issued for the practitioner pursuant to subsection (g). The identification number so assigned shall be appropriate to preserve the confidentiality of patients for whom the practitioner has dispensed narcotic drugs under a waiver under subparagraph (A).

(iii) Not later than 45 days after the date on which the Secretary receives a notification under subparagraph (B), the Secretary shall make a determination of whether the practitioner involved meets all requirements for a waiver under subparagraph (B) and shall forward such determination to the Attorney General. If the Secretary fails to make such determination by the end of the such 45-day period, the Attorney General shall assign the practitioner an identification number described in clause (ii) at the end of such period.

(E)(i) If a practitioner is not registered under paragraph (1) and, in violation of the conditions specified in subparagraphs (B) through (D), dispenses narcotic drugs in schedule III, IV, or V or combinations of such drugs for maintenance treatment or detoxification treatment, the Attorney General may, for purposes of section 304(a)(4), consider the practitioner to have committed an act that renders the registration of the practitioner pursuant to subsection (g) to be inconsistent with the public interest.

(ii)(I) Upon the expiration of 45 days from the date on which the Secretary receives a notification under subparagraph (B), a practitioner who in good faith submits a notification under subparagraph (B) and reasonably believes that the conditions specified in subparagraphs (B) through (D) have been met shall, in dispensing narcotic drugs in schedule III, IV, or V or combinations of such drugs for maintenance treatment or detoxification treatment, be considered to have a waiver under subparagraph (A) until notified otherwise by the Secretary, except that such a practitioner may commence to prescribe or dispense such narcotic drugs for such purposes prior to the expiration of such 45-day period if it facilitates the treatment of an individual patient and both the Secretary and the Attorney General are notified by the practitioner of the intent to commence prescribing or dispensing such narcotic drugs.

(II) For purposes of subclause (I), the publication in the Federal Register of an adverse determination by the Secretary pursuant to subparagraph (C)(ii) shall (with respect to the narcotic drug or combination involved) be considered to be a notification provided by the Secretary to practitioners, effective upon the expiration of the 30-day period beginning on the date on which the adverse determination is so published.

(F)(i) With respect to the dispensing of narcotic drugs in schedule III, IV, or V or combinations of such drugs to patients for maintenance or detoxification treatment, a practitioner may, in his or her discretion, dispense such drugs or combinations for such treatment under a registration under paragraph (1) or a waiver under subparagraph (A) (subject to meeting the applicable conditions).

(ii) This paragraph may not be construed as having any legal effect on the conditions for obtaining a registration under paragraph (1), including with respect to the number of patients who may be served under such a registration.

(G) For purposes of this paragraph:

(i) The term "group practice" has the meaning given such term in section 1877(h)(4) of the Social Security Act.

(ii) The term "qualifying physician" means a physician who is licensed under State law and who meets one or more of the following conditions:

(I) The physician holds a board certification in addiction psychiatry or addiction medicine from the American Board of Medical Specialties.

(II) The physician holds an addiction certification or board certification from the American Society of Addiction Medicine or the American Board of Addiction Medicine.

(III) The physician holds a board certification in addiction medicine from the American Osteopathic Association.

(IV) The physician has, with respect to the treatment and management of opiate-dependent patients, completed not less than 8 hours of training (through classroom situations, seminars at professional society meetings, electronic communications, or otherwise) that is provided by the American Society of Addiction Medicine, the American Academy of Addiction Psychiatry, the American Medical Association, the American Osteopathic Association, the American Psychiatric Association, or any other organization that the Secretary determines is appropriate for purposes of this subclause. Such training shall include—

(aa) opioid maintenance and detoxification;

(bb) appropriate clinical use of all drugs approved by the Food and Drug Administration for the treatment of opioid use disorder;

(cc) initial and periodic patient assessments (including substance use monitoring);

(dd) individualized treatment planning, overdose reversal, and relapse prevention;

(ee) counseling and recovery support services;

(ff) staffing roles and considerations;

(gg) diversion control; and

(hh) other best practices, as identified by the Secretary.

(V) The physician has participated as an investigator in one or more clinical trials leading to the approval of a narcotic drug in schedule III, IV, or V for maintenance or detoxification treatment, as demonstrated by a statement submitted to the Secretary by the sponsor of such approved drug.

(VI) The physician has such other training or experience as the State medical licensing board (of the State in which the physician will provide maintenance or detoxification treatment) considers to demonstrate the ability of the physician to treat and manage opiate-dependent patients.

(VII) The physician has such other training or experience as the Secretary considers to demonstrate the ability of the physician to treat and manage opiate-dependent patients. Any criteria of the Secretary under this subclause shall be established by regulation. Any such criteria are effective only for 3 years after the date on which the criteria are promulgated, but may be extended for such additional discrete 3-year periods as the Secretary considers appropriate for purposes of this subclause. Such an extension of criteria may only be effectuated through a statement published in the Federal Register by the Secretary during the

30-day period preceding the end of the 3-year period involved.

(VIII) The physician graduated in good standing from an accredited school of allopathic medicine or osteopathic medicine in the United States during the 5-year period immediately preceding the date on which the physician submits to the Secretary a written notification under subparagraph (B) and successfully completed a comprehensive allopathic or osteopathic medicine curriculum or accredited medical residency that—

(aa) included not less than 8 hours of training on treating and managing opioid-dependent patients; and

(bb) included, at a minimum—

(AA) the training described in items (aa) through (gg) of subclause (IV); and

(BB) training with respect to any other best practice the Secretary determines should be included in the curriculum, which may include training on pain management, including assessment and appropriate use of opioid and non-opioid alternatives.

(iii) The term "qualifying practitioner" means—

(I) a qualifying physician, as defined in clause (ii);

(II) a qualifying other practitioner, as defined in clause (iv), who is a nurse practitioner or physician assistant; or

(III) for the period beginning on October 1, 2018, and ending on October 1, 2023, a qualifying other practitioner, as defined in clause (iv), who is a clinical nurse specialist, certified registered nurse anesthetist, or certified nurse midwife.

(iv) The term "qualifying other practitioner" means a nurse practitioner, clinical nurse specialist, certified registered nurse anesthetist, certified nurse midwife, or physician assistant who satisfies each of the following:

(I) The nurse practitioner, clinical nurse specialist, certified registered nurse anesthetist, certified nurse midwife, or physician assistant is licensed under State law to prescribe schedule III, IV, or V medications for the treatment of pain.

(II) The nurse practitioner, clinical nurse specialist, certified registered nurse anesthetist, certified nurse midwife, or physician assistant has—

(aa) completed not fewer than 24 hours of initial training addressing each of the topics listed in clause (ii)(IV) (through classroom situations, seminars at professional society meetings, electronic communications, or otherwise) provided by the American Society of Addiction Medicine, the American Academy of Addiction Psychiatry, the American Medical Association, the American Osteopathic Association, the American Nurses Credentialing Center, the American Psychiatric Association, the American Association of Nurse Practitioners, the American Academy of Physician Assistants, or any other organization that the Secretary determines is appropriate for purposes of this subclause; or

(bb) has such other training or experience as the Secretary determines will demonstrate the ability of the nurse practitioner, clinical nurse specialist, certified registered nurse anesthetist, certified nurse midwife, or physician assistant to treat and manage opiate-dependent patients.

(III) The nurse practitioner, clinical nurse specialist, certified registered nurse anesthetist, certified nurse midwife, or physician assistant is supervised by, or works in collaboration with, a qualifying physician, if the nurse practitioner, clinical nurse specialist, certified registered nurse anesthetist, certified nurse midwife, or physician assistant is required by State law to prescribe medications for the treatment of opioid use disorder in collaboration with or under the supervision of a physician.

The Secretary may, by regulation, revise the requirements for being a qualifying other practitioner under this clause.

(H)(i) In consultation with the Administrator of the Drug Enforcement Administration, the Administrator of the Substance Abuse and Mental Health Services Administration, the Director of the National Institute on Drug Abuse, and the Commissioner of Food and Drugs, the Secretary shall issue regulations (through notice and comment rulemaking) or issue practice guidelines to address the following:

(I) Approval of additional credentialing bodies and the responsibilities of additional credentialing bodies.

(II) Additional exemptions from the requirements of this paragraph and any regulations under this paragraph.

(III) Such other elements of the requirements under this paragraph as the Secretary determines necessary for purposes of implementing such requirements.

Nothing in such regulations or practice guidelines may authorize any Federal official or employee to exercise supervision or control over the practice of medicine or the manner in which medical services are provided.

(ii) Not later than 18 months after the date of enactment of the Opioid Use Disorder Treatment Expansion and Modernization Act, the Secretary shall update the treatment improvement protocol containing best practice guidelines for the treatment of opioid-dependent patients in office-based settings. The Secretary shall update such protocol in consultation with experts in opioid use disorder research and treatment.

(I) Notwithstanding section 708, nothing in this paragraph shall be construed to preempt any State law that—

(i) permits a qualifying practitioner to dispense narcotic drugs in schedule III, IV, or V, or combinations of such drugs, for maintenance or detoxification treatment in accordance with this paragraph to a total number of patients that is more than 30 or less than the total number applicable to the qualifying practitioner under subparagraph (B)(iii)(II) if a State enacts a law modifying such total number and the Attorney General is notified by the State of such modification; or

(ii) requires a qualifying practitioner to comply with additional requirements relating to the dispensing of narcotic drugs in schedule III, IV, or V, or combinations of such drugs, includ-

ing requirements relating to the practice setting in which the qualifying practitioner practices and education, training, and reporting requirements.

(i) The Attorney General shall register an applicant to distribute a list I chemical unless the Attorney General determines that registration of the applicant is inconsistent with the public interest. Registration under this subsection shall not be required for the distribution of a drug product that is exempted under clause (iv) or (v) of section 102(39)(A). In determining the public interest for the purposes of this subsection, the Attorney General shall consider—

(1) maintenance by the applicant of effective controls against diversion of listed chemicals into other than legitimate channels;

(2) compliance by the applicant with applicable Federal, State, and local law;

(3) any prior conviction record of the applicant under Federal or State laws relating to controlled substances or to chemicals controlled under Federal or State law;

(4) any past experience of the applicant in the manufacture and distribution of chemicals; and

(5) such other factors as are relevant to and consistent with the public health and safety.

(j)(1) For purposes of registration to manufacture a controlled substance under subsection (e) for use only in a clinical trial, the Attorney General shall register the applicant, or serve an order to show cause upon the applicant in accordance with section 304(c), not later than 180 days after the date on which the application is accepted for filing.

(2) For purposes of registration to manufacture a controlled substance under subsection (a) for use only in a clinical trial, the Attorney General shall, in accordance with the regulations issued by the Attorney General, issue a notice of application not later than 90 days after the application is accepted for filing. Not later than 90 days after the date on which the period for comment pursuant to such notice ends, the Attorney General shall register the applicant, or serve an order to show cause upon the applicant in accordance with section 304(c), unless the Attorney General has granted a hearing on the application under section 1008(i) of the Controlled Substances Import and Export Act.

(k) EMERGENCY MEDICAL SERVICES THAT ADMINISTER CONTROLLED SUBSTANCES.—

(1) REGISTRATION.—For the purpose of enabling emergency medical services professionals to administer controlled substances in schedule II, III, IV, or V to ultimate users receiving emergency medical services in accordance with the requirements of this subsection, the Attorney General—

(A) shall register an emergency medical services agency if the agency submits an application demonstrating it is authorized to conduct such activity under the laws of each State in which the agency practices; and

(B) may deny an application for such registration if the Attorney General determines that the issuance of such registration would be inconsistent with the requirements of this subsection or the public interest based on the factors listed in subsection (g).

(2) OPTION FOR SINGLE REGISTRATION.—In registering an emergency medical services agency pursuant to paragraph (1), the Attorney General shall allow such agency the option of a single registration in each State where the agency administers controlled substances in lieu of requiring a separate registration for each location of the emergency medical services agency.

(3) HOSPITAL-BASED AGENCY.—If a hospital-based emergency medical services agency is registered under subsection (g), the agency may use the registration of the hospital to administer controlled substances in accordance with this subsection without being registered under this subsection.

(4) ADMINISTRATION OUTSIDE PHYSICAL PRESENCE OF MEDICAL DIRECTOR OR AUTHORIZING MEDICAL PROFESSIONAL.—Emergency medical services professionals of a registered emergency medical services agency may administer controlled substances in schedule II, III, IV, or V outside the physical presence of a medical director or authorizing medical professional in the course of providing emergency medical services if the administration is—

(A) authorized by the law of the State in which it occurs; and

(B) pursuant to—

(i) a standing order that is issued and adopted by one or more medical directors of the agency, including any such order that may be developed by a specific State authority; or

(ii) a verbal order that is—

(I) issued in accordance with a policy of the agency; and

(II) provided by a medical director or authorizing medical professional in response to a request by the emergency medical services professional with respect to a specific patient—

(aa) in the case of a mass casualty incident; or

(bb) to ensure the proper care and treatment of a specific patient.

(5) DELIVERY.—A registered emergency medical services agency may deliver controlled substances from a registered location of the agency to an unregistered location of the agency only if the agency—

(A) designates the unregistered location for such delivery; and

(B) notifies the Attorney General at least 30 days prior to first delivering controlled substances to the unregistered location.

(6) STORAGE.—A registered emergency medical services agency may store controlled substances—

(A) at a registered location of the agency;

(B) at any designated location of the agency or in an emergency services vehicle situated at a registered or designated location of the agency; or

(C) in an emergency medical services vehicle used by the agency that is—

(i) traveling from, or returning to, a registered or designated location of the agency in the course of responding to an emergency; or

(ii) otherwise actively in use by the agency under circumstances that provide for security of the controlled substances consistent with the requirements established by regulations of the Attorney General.

(7) NO TREATMENT AS DISTRIBUTION.—The delivery of controlled substances by a registered emergency medical services agency pursuant to this subsection shall not be treated as distribution for purposes of section 308.

(8) RESTOCKING OF EMERGENCY MEDICAL SERVICES VEHICLES AT A HOSPITAL.—Notwithstanding paragraph (13)(J), a registered emergency medical services agency may receive controlled substances from a hospital for purposes of restocking an emergency medical services vehicle following an emergency response, and without being subject to the requirements of section 308, provided all of the following conditions are satisfied:

(A) The registered or designated location of the agency where the vehicle is primarily situated maintains a record of such receipt in accordance with paragraph (9).

(B) The hospital maintains a record of such delivery to the agency in accordance with section 307.

(C) If the vehicle is primarily situated at a designated location, such location notifies the registered location of the agency within 72 hours of the vehicle receiving the controlled substances.

(9) MAINTENANCE OF RECORDS.—

(A) IN GENERAL.—A registered emergency medical services agency shall maintain records in accordance with subsections (a) and (b) of section 307 of all controlled substances that are received, administered, or otherwise disposed of pursuant to the agency's registration, without regard to subsection 307(c)(1)(B).

(B) REQUIREMENTS.—Such records—

(i) shall include records of deliveries of controlled substances between all locations of the agency; and

(ii) shall be maintained, whether electronically or otherwise, at each registered and designated location of the agency where the controlled substances involved are received, administered, or otherwise disposed of.

(10) OTHER REQUIREMENTS.—A registered emergency medical services agency, under the supervision of a medical director, shall be responsible for ensuring that—

(A) all emergency medical services professionals who administer controlled substances using the agency's registration act in accordance with the requirements of this subsection;

(B) the recordkeeping requirements of paragraph (9) are met with respect to a registered location and each designated location of the agency;

(C) the applicable physical security requirements established by regulation of the Attorney General are complied with wherever controlled substances are stored by the agency in accordance with paragraph (6); and

(D) the agency maintains, at a registered location of the agency, a record of the standing orders issued or adopted in accordance with paragraph (9).

(11) REGULATIONS.—The Attorney General may issue regulations—

(A) specifying, with regard to delivery of controlled substances under paragraph (5)—

(i) the types of locations that may be designated under such paragraph; and

(ii) the manner in which a notification under paragraph (5)(B) must be made;

(B) specifying, with regard to the storage of controlled substances under paragraph (6), the manner in which such substances must be stored at registered and designated locations, including in emergency medical service vehicles; and

(C) addressing the ability of hospitals, emergency medical services agencies, registered locations, and designated locations to deliver controlled substances to each other in the event of—

(i) shortages of such substances;

(ii) a public health emergency; or

(iii) a mass casualty event.

(12) RULE OF CONSTRUCTION.—Nothing in this subsection shall be construed—

(A) to limit the authority vested in the Attorney General by other provisions of this title to take measures to prevent diversion of controlled substances; or

(B) to override the authority of any State to regulate the provision of emergency medical services consistent with this subsection.

(13) DEFINITIONS.—In this section:

(A) The term "authorizing medical professional" means an emergency or other physician, or another medical professional (including an advanced practice registered nurse or physician assistant)—

(i) who is registered under this Act;

(ii) who is acting within the scope of the registration; and

(iii) whose scope of practice under a State license or certification includes the ability to provide verbal orders.

(B) The term "designated location" means a location designated by an emergency medical services agency under paragraph (5).

(C) The term "emergency medical services" means emergency medical response and emergency mobile medical services provided outside of a fixed medical facility.

(D) The term "emergency medical services agency" means an organization providing emergency medical services, including such an organization that—

(i) is governmental (including fire-based and hospital-based agencies), nongovernmental (including hospital-based agencies), private, or volunteer-based;

(ii) provides emergency medical services by ground, air, or otherwise; and

(iii) is authorized by the State in which the organization is providing such services to provide emergency medical care, including the administering of controlled substances, to members of the general public on an emergency basis.

(E) The term "emergency medical services professional" means a health care professional (including a nurse, paramedic, or emergency medical technician) licensed or certified by the State in which the professional practices and credentialed by a medical director of the respective emergency medical services agency to provide emergency medical services within the scope of the professional's State license or certification.

(F) The term "emergency medical services vehicle" means an ambulance, fire apparatus, supervisor truck, or other vehicle used by an emergency medical services agency for the purpose of providing or facilitating emergency medical care and transport or transporting controlled substances to and from the registered and designated locations.

(G) The term "hospital-based" means, with respect to an agency, owned or operated by a hospital.

(H) The term "medical director" means a physician who is registered under subsection (g) and provides medical oversight for an emergency medical services agency.

(I) The term "medical oversight" means supervision of the provision of medical care by an emergency medical services agency.

(J) The term "registered emergency medical services agency" means—

(i) an emergency medical services agency that is registered pursuant to this subsection; or

(ii) a hospital-based emergency medical services agency that is covered by the registration of the hospital under subsection (g).

(K) The term "registered location" means a location that appears on the certificate of registration issued to an emergency medical services agency under this subsection or subsection (g), which shall be where the agency receives controlled substances from distributors.

(L) The term "specific State authority" means a governmental agency or other such authority, including a regional oversight and coordinating body, that, pursuant to State law or regulation, develops clinical protocols regarding the delivery of emergency medical services in the geographic jurisdiction of such agency or authority within the State that may be adopted by medical directors.

(M) The term "standing order" means a written medical protocol in which a medical director determines in advance the medical criteria that must be met before administering controlled substances to individuals in need of emergency medical services.

(N) The term "verbal order" means an oral directive that is given through any method of communication including by radio or telephone, directly to an emergency medical services professional, to contemporaneously administer a controlled substance to individuals in need of emergency medical services outside the physical presence of the medical director or authorizing medical professional.

(l) In this section, the phrase "factors as may be relevant to and consistent with the public health and safety" means factors that are relevant to and consistent with the findings contained in section 101.

[(l)] *(m)* REQUIRED TRAINING FOR PRESCRIBERS.—

(1) TRAINING REQUIRED.—As a condition on registration under this section to dispense controlled substances in schedule II, III, IV, or V, the Attorney General shall require any qualified practitioner, beginning with the first applicable registration for the practitioner, to meet the following:

(A) If the practitioner is a physician (as defined under section 1861(r) of the Social Security Act) and the practitioner meets one or more of the following conditions:

(i) The physician holds a board certification in addiction psychiatry or addiction medicine from the American Board of Medical Specialties.

(ii) The physician holds a board certification from the American Board of Addiction Medicine.

(iii) The physician holds a board certification in addiction medicine from the American Osteopathic Association.

(iv) The physician has, with respect to the treatment and management of patients with opioid or other substance use disorders, or the safe pharmacological management of dental pain and screening, brief intervention, and referral for appropriate treatment of patients with or at risk of developing opioid or other substance use disorders, completed not less than 8 hours of training (through classroom situations, seminars at professional society meetings, electronic communications, or otherwise) that is provided by—

(I) the American Society of Addiction Medicine, the American Academy of Addiction Psychiatry, the American Medical Association, the American Osteopathic Association, the American Dental Association, the American Association of Oral and Maxillofacial Surgeons, the American Psychiatric Association, or any other organization accredited by the Accreditation Council for Continuing Medical Education (ACCME) or the Commission for Continuing Education Provider Recognition (CCEPR);

(II) any organization accredited by a State medical society accreditor that is recognized by the ACCME or the CCEPR;

(III) any organization accredited by the American Osteopathic Association to provide continuing medical education; or

(IV) any organization approved by the Assistant Secretary for Mental Health and Substance Use, the ACCME, or the CCEPR.

(v) The physician graduated in good standing from an accredited school of allopathic medicine, osteopathic medicine, dental surgery, or dental medicine in the United States during the 5-year period immediately preceding the date on which the physician first registers or renews under this section and has successfully completed a comprehensive allopathic or osteopathic medicine curriculum or accredited medical residency or dental surgery or dental medicine curriculum that included not less than 8 hours of training on—

(I) treating and managing patients with opioid or other substance use disorders, including the appropriate clinical use of all drugs approved by the Food and Drug Administration for the treatment of a substance use disorder; or

(II) the safe pharmacological management of dental pain and screening, brief intervention, and referral for appropriate treatment of patients with or at risk of developing opioid and other substance use disorders.

(B) If the practitioner is not a physician (as defined under section 1861(r) of the Social Security Act), the practitioner is legally authorized by the State to dispense controlled substances under schedule II, III, IV, or V and is dispensing such substances within such State in accordance with all applicable State laws, and the practitioner meets one or more of the following conditions:

(i) The practitioner has completed not fewer than 8 hours of training with respect to the treatment and management of patients with opioid or other substance use disorders (through classroom situations, seminars at professional society meetings, electronic communications, or otherwise) provided by the American Society of Addiction Medicine, the American Academy of Addiction Psychiatry, the American Medical Association, the American Osteopathic Association, the American Nurses Credentialing Center, the American Psychiatric Association, the American Association of Nurse Practitioners, the American Academy of Physician Associates, or any other organization approved or accredited by the Assistant Secretary for Mental Health and Substance Use or the Accreditation Council for Continuing Medical Education.

(ii) The practitioner has graduated in good standing from an accredited physician assistant school or accredited school of advanced practice nursing in the United States during the 5-year period immediately preceding the date on which the practitioner first registers or renews under this section and has successfully completed a comprehensive physician assistant or advanced practice nursing curriculum that included not fewer than 8 hours of training on treating and

managing patients with opioid and other substance use disorders, including the appropriate clinical use of all drugs approved by the Food and Drug Administration for the treatment of a substance use disorder.

(2) ONE-TIME TRAINING.—

(A) IN GENERAL.—The Attorney General shall not require any qualified practitioner to complete the training described in clause (iv) or (v) of paragraph (1)(A) or clause (i) or (ii) of paragraph (1)(B) more than once.

(B) NOTIFICATION.—Not later than 90 days after the date of the enactment of the Restoring Hope for Mental Health and Well-Being Act of 2022, the Attorney General shall provide to qualified practitioners a single written, electronic notification of the training described in clauses (iv) and (v) of paragraph (1)(A) or clauses (i) and (ii) of paragraph (1)(B).

(3) RULE OF CONSTRUCTION.—Nothing in this subsection shall be construed—

(A) to preclude the use, by a qualified practitioner, of training received pursuant to this subsection to satisfy registration requirements of a State or for some other lawful purpose; or

(B) to preempt any additional requirements by a State related to the dispensing of controlled substances under schedule II, III, IV, or V.

(4) DEFINITIONS.—In this section:

(A) FIRST APPLICABLE REGISTRATION.—The term "first applicable registration" means the first registration or renewal of registration by a qualified practitioner under this section that occurs on or after the date that is 180 days after the date of enactment of the Restoring Hope for Mental Health and Well-Being Act of 2022.

(B) QUALIFIED PRACTITIONER.—In this subsection, the term "qualified practitioner" means a practitioner who—

(i) is licensed under State law to prescribe controlled substances; and

(ii) is not solely a veterinarian.

(n) 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 De-

partment 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 research:

(I) The chemical name of the substance.

(II) The quantity of the substance to be used in the research.

(III) Demonstration that the research 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 intramural research project, by identifying the sponsoring agency and supplying the number of the grant, contract, cooperative agreement, other transaction, or project; or

(bb) in the case of an application under section 505(i) of the Federal Food, Drug, and Cosmetic Act, by supplying the application number and the sponsor 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 supplemental 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 consistent with the scope of the research that was the subject of the notification under paragraph (3).

(6) IMPORTATION AND EXPORTATION REQUIREMENTS NOT AFFECTED.—Nothing in this subsection alters the requirements of part A of title III, regarding the importation and exportation of controlled substances.

(o) 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.

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PART D—OFFENSES AND PENALTIES

PROHIBITED ACTS A—PENALTIES

SEC. 401. (a) Except as authorized by this title, it shall be unlawful for any person knowingly or intentionally—

(1) to manufacture, distribute, or dispense, or possess with intent to manufacture, distribute, or dispense, a controlled substance; or

(2) to create, distribute, or dispense, or possess with intent to distribute or dispense, a counterfeit substance.

(b) Except as otherwise provided in section 409, 418, 419, or 420 any person who violates subsection (a) of this section shall be sentenced as follows:

(1)(A) In the case of a violation of subsection (a) of this section involving—

(i) 1 kilogram or more of a mixture or substance containing a detectable amount of heroin;

(ii) 5 kilograms or more of a mixture or substance containing a detectable amount of—

(I) coca leaves, except coca leaves and extracts of coca leaves from which cocaine, ecgonine, and derivatives of ecgonine or their salts have been removed;

(II) cocaine, its salts, optical and geometric isomers, and salts of isomers;

(III) ecgonine, its derivatives, their salts, isomers, and salts of isomers; or

(IV) any compound, mixture, or preparation which contains any quantity of any of the substances referred to in subclauses (I) through (III);

(iii) 280 grams or more of a mixture or substance described in clause (ii) which contains cocaine base;

(iv) 100 grams or more of phencyclidine (PCP) or 1 kilogram or more of a mixture or substance containing a detectable amount of phencyclidine (PCP);

(v) 10 grams or more of a mixture or substance containing a detectable amount of lysergic acid diethylamide (LSD);

(vi) 400 grams or more of a mixture or substance containing a detectable amount of N-phenyl-N-[1-(2-phenylethyl)-4-piperidinyl] propanamide or 100 grams or more of a mixture or substance containing a detectable amount of any analogue of N-phenyl-N-[1-(2-phenylethyl)-4-piperidinyl] propanamide *or a fentanyl-related substance*;

(vii) 1000 kilograms or more of a mixture or substance containing a detectable amount of marihuana, or 1,000 or more marihuana plants regardless of weight; or

(viii) 50 grams or more of methamphetamine, its salts, isomers, and salts of its isomers or 500 grams or more of a mixture or substance containing a detectable amount of methamphetamine, its salts, isomers, or salts of its isomers;

such person shall be sentenced to a term of imprisonment which may not be less than 10 years or more than life and if death or serious bodily injury results from the use of such substance shall be not less than 20 years or more than life, a fine not to exceed the greater of that authorized in accordance with the provisions of title 18, United States Code, or $10,000,000 if the defendant is an individual or $50,000,000 if the defendant is other than an individual, or both. If any person commits such a violation after a prior conviction for a serious drug felony or serious violent felony has become final, such person shall be sentenced to a term of imprisonment of not less than 15 years and not more than life imprison-

ment and if death or serious bodily injury results from the use of such substance shall be sentenced to life imprisonment, a fine not to exceed the greater of twice that authorized in accordance with the provisions of title 18, United States Code, or $20,000,000 if the defendant is an individual or $75,000,000 if the defendant is other than an individual, or both. If any person commits a violation of this subparagraph or of section 409, 418, 419, or 420 after 2 or more prior convictions for a serious drug felony or serious violent felony have become final, such person shall be sentenced to a term of imprisonment of not less than 25 years and fined in accordance with the preceding sentence. Notwithstanding section 3583 of title 18, any sentence under this subparagraph shall, in the absence of such a prior conviction, impose a term of supervised release of at least 5 years in addition to such term of imprisonment and shall, if there was such a prior conviction, impose a term of supervised release of at least 10 years in addition to such term of imprisonment. Notwithstanding any other provision of law, the court shall not place on probation or suspend the sentence of any person sentenced under this subparagraph. No person sentenced under this subparagraph shall be eligible for parole during the term of imprisonment imposed therein.

(B) In the case of a violation of subsection (a) of this section involving—

(i) 100 grams or more of a mixture or substance containing a detectable amount of heroin;

(ii) 500 grams or more of a mixture or substance containing a detectable amount of—

(I) coca leaves, except coca leaves and extracts of coca leaves from which cocaine, ecgonine, and derivatives of ecgonine or their salts have been removed;

(II) cocaine, its salts, optical and geometric isomers, and salts of isomers;

(III) ecgonine, its derivatives, their salts, isomers, and salts of isomers; or

(IV) any compound, mixture, or preparation which contains any quantity of any of the substances referred to in subclauses (I) through (III);

(iii) 28 grams or more of a mixture or substance described in clause (ii) which contains cocaine base;

(iv) 10 grams or more of phencyclidine (PCP) or 100 grams or more of a mixture or substance containing a detectable amount of phencyclidine (PCP);

(v) 1 gram or more of a mixture or substance containing a detectable amount of lysergic acid diethylamide (LSD);

(vi) 40 grams or more of a mixture or substance containing a detectable amount of N-phenyl-N-[1-(2-phenylethyl)-4-piperidinyl] propanamide or 10 grams or more of a mixture or substance containing a detectable amount of any analogue of N-phenyl-N-[1-(2-phenylethyl)-4-piperidinyl] propanamide *or a fentanyl-related substance*;

(vii) 100 kilograms or more of a mixture or substance containing a detectable amount of marihuana, or 100 or more marihuana plants regardless of weight; or

(viii) 5 grams or more of methamphetamine, its salts, isomers, and salts of its isomers or 50 grams or more of a mixture

or substance containing a detectable amount of methamphetamine, its salts, isomers, or salts of its isomers;

such person shall be sentenced to a term of imprisonment which may not be less than 5 years and not more than 40 years and if death or serious bodily injury results from the use of such substance shall be not less than 20 years or more than life, a fine not to exceed the greater of that authorized in accordance with the provisions of title 18, United States Code, or $5,000,000 if the defendant is an individual or $25,000,000 if the defendant is other than an individual, or both. If any person commits such a violation after a prior conviction for a serious drug felony or serious violent felony has become final, such person shall be sentenced to a term of imprisonment which may not be less than 10 years and not more than life imprisonment and if death or serious bodily injury results from the use of such substance shall be sentenced to life imprisonment, a fine not to exceed the greater of twice that authorized in accordance with the provisions of title 18, United States Code, or $8,000,000 if the defendant is an individual or $50,000,000 if the defendant is other than an individual, or both. Notwithstanding section 3583 of title 18, any sentence under this subparagraph shall, in the absence of such a prior conviction, include a term of supervised release of at least 4 years in addition to such term of imprisonment and shall, if there was such a prior conviction, include a term of supervised release of at least 8 years in addition to such term of imprisonment. Notwithstanding any other provision of law, the court shall not place on probation or suspend the sentence of any person sentenced under this subparagraph. No person sentenced under this subparagraph shall be eligible for parole during the term of imprisonment imposed therein.

(C) In the case of a controlled substance in schedule I or II, gamma hydroxybutyric acid (including when scheduled as an approved drug product for purposes of section 3(a)(1)(B) of the Hillory J. Farias and Samantha Reid Date-Rape Drug Prohibition Act of 2000), or 1 gram of flunitrazepam, except as provided in subparagraphs (A), (B), and (D), such person shall be sentenced to a term of imprisonment of not more than 20 years and if death or serious bodily injury results from the use of such substance shall be sentenced to a term of imprisonment of not less than twenty years or more than life, a fine not to exceed the greater of that authorized in accordance with the provisions of title 18, United States Code, or $1,000,000 if the defendant is an individual or $5,000,000 if the defendant is other than an individual, or both. If any person commits such a violation after a prior conviction for a felony drug offense has become final, such person shall be sentenced to a term of imprisonment of not more than 30 years and if death or serious bodily injury results from the use of such substance shall be sentenced to life imprisonment, a fine not to exceed the greater of twice that authorized in accordance with the provisions of title 18, United States Code, or $2,000,000 if the defendant is an individual or $10,000,000 if the defendant is other than an individual, or both. Notwithstanding section 3583 of title 18, any sentence imposing a term of imprisonment under this paragraph shall, in the absence of such a prior conviction, impose a term of supervised release of at least 3 years in addition to such term of imprisonment and shall, if there was such a prior conviction, impose a term of supervised

release of at least 6 years in addition to such term of imprisonment. Notwithstanding any other provision of law, the court shall not place on probation or suspend the sentence of any person sentenced under the provisions of this subparagraph which provide for a mandatory term of imprisonment if death or serious bodily injury results, nor shall a person so sentenced be eligible for parole during the term of such a sentence.

(D) In the case of less than 50 kilograms of marihuana, except in the case of 50 or more marihuana plants regardless of weight, 10 kilograms of hashish, or one kilogram of hashish oil, such person shall, except as provided in paragraphs (4) and (5) of this subsection, be sentenced to a term of imprisonment of not more than 5 years, a fine not to exceed the greater of that authorized in accordance with the provisions of title 18, United States Code, or $250,000 if the defendant is an individual or $1,000,000 if the defendant is other than an individual, or both. If any person commits such a violation after a prior conviction for a felony drug offense has become final, such person shall be sentenced to a term of imprisonment of not more than 10 years, a fine not to exceed the greater of twice that authorized in accordance with the provisions of title 18, United State Code, or $500,000 if the defendant is an individual or $2,000,000 if the defendant is other than an individual, or both. Notwithstanding section 3583 of title 18, any sentence imposing a term of imprisonment under this paragraph shall, in the absence of such a prior conviction, impose a special parole term of at least 2 years in addition to such term of imprisonment and shall, if there was such a prior conviction, impose a term of supervised release of at least 4 years in addition to such term of imprisonment.

(E)(i) Except as provided in subparagraphs (C) and (D), in the case of any controlled substance in schedule III, such person shall be sentenced to a term of imprisonment of not more than 10 years and if death or serious bodily injury results from the use of such substance shall be sentenced to a term of imprisonment of not more than 15 years, a fine not to exceed the greater of that authorized in accordance with the provisions of title 18, United States Code, or $500,000 if the defendant is an individual or $2,500,000 if the defendant is other than an individual, or both.

(ii) If any person commits such a violation after a prior conviction for a felony drug offense has become final, such person shall be sentenced to a term of imprisonment of not more than 20 years and if death or serious bodily injury results from the use of such substance shall be sentenced to a term of imprisonment of not more than 30 years, a fine not to exceed the greater of twice that authorized in accordance with the provisions of title 18, United States Code, or $1,000,000 if the defendant is an individual or $5,000,000 if the defendant is other than an individual, or both.

(iii) Any sentence imposing a term of imprisonment under this subparagraph shall, in the absence of such a prior conviction, impose a term of supervised release of at least 2 years in addition to such term of imprisonment and shall, if there was such a prior conviction, impose a term of supervised release of at least 4 years in addition to such term of imprisonment.

(2) In the case of a controlled substance in schedule IV, such person shall be sentenced to a term of imprisonment of not more than

5 years, a fine not to exceed the greater of that authorized in accordance with the provisions of title 18, United States Code, or $250,000 if the defendant is an individual or $1,000,000 if the defendant is other than an individual, or both. If any person commits such a violation after a prior conviction for a felony drug offense has become final, such person shall be sentenced to a term of imprisonment of not more than 10 years, a fine not to exceed the greater of twice the authorized in accordance with the provisions of title 18, United States Code, or $500,000 if the defendant is an individual or $2,000,000 if the defendant is other than an individual, or both. Any sentence imposing a term of imprisonment under this paragraph shall, in the absence of such a prior conviction, impose a term of supervised release of at least one year in addition to such term of imprisonment and shall, if there was such a prior conviction, impose a term of supervised release of at least 2 years in addition to such term of imprisonment.

(3) In the case of a controlled substance in schedule V, such person shall be sentenced to a term of imprisonment of not more than 1 year, a fine not to exceed the greater of that authorized in accordance with the provisions of title 18, United States Code, or $100,000 if the defendant is an individual or $250,000 if the defendant is other than an individual, or both. If any person commits such a violation after a prior conviction for a felony drug offense has become final, such person shall be sentenced to a term of imprisonment of not more than 4 years, a fine not to exceed the provisions of title 18, United States Code, or $200,000 if the defendant is an individual or $500,000 if the defendant is other than an individual, or both. Any sentence imposing a term of imprisonment under this paragraph may, if there was a prior conviction, impose a term of supervised release of not more than 1 year, in addition to such term of imprisonment.

(4) Notwithstanding paragraph (1)(D) of this subsection, any person who violates subsection (a) of this section by distributing a small amount of marihuana for no remuneration shall be treated as provided in section 404 and section 3607 of title 18, United States Code.

(5) Any person who violates subsection (a) of this section by cultivating or manufacturing a controlled substance on Federal property shall be imprisoned as provided in this subsection and shall be fined any amount not to exceed—

(A) the amount authorized in accordance with this section;

(B) the amount authorized in accordance with the provisions of title 18, United States Code;

(C) $500,000 if the defendant is an individual; or

(D) $1,000,000 if the defendant is other than an individual; or both.

(6) Any person who violates subsection (a), or attempts to do so, and knowingly or intentionally uses a poison, chemical, or other hazardous substance on Federal land, and, by such use—

(A) creates a serious hazard to humans, wildlife, or domestic animals,

(B) degrades or harms the environment or natural resources, or

(C) pollutes an aquifer, spring, stream, river, or body of water,

shall be fined in accordance with title 18, United States Code, or imprisoned not more than five years, or both.

(7) PENALTIES FOR DISTRIBUTION.—

(A) IN GENERAL.—Whoever, with intent to commit a crime of violence, as defined in section 16 of title 18, United States Code (including rape), against an individual, violates subsection (a) by distributing a controlled substance or controlled substance analogue to that individual without that individual's knowledge, shall be imprisoned not more than 20 years and fined in accordance with title 18, United States Code.

(B) DEFINITION.—For purposes of this paragraph, the term "without that individual's knowledge" means that the individual is unaware that a substance with the ability to alter that individual's ability to appraise conduct or to decline participation in or communicate unwillingness to participate in conduct is administered to the individual.

(c) Any person who knowingly or intentionally—

(1) possesses a listed chemical with intent to manufacture a controlled substance except as authorized by this title;

(2) possesses or distributes, a listed chemical knowing, or having reasonable cause to believe, that the listed chemical will be used to manufacture a controlled substance except as authorized by this title; or

(3) with the intent of causing the evasion of the recordkeeping or reporting requirements of section 310, or the regulations issued under that section, receives or distributes a reportable amount of any listed chemical in units small enough so that the making of records or filing of reports under that section is not required;

shall be fined in accordance with title 18, United States Code, or imprisoned not more than 20 years in the case of a violation of paragraph (1) or (2) involving a list I chemical or not more than 10 years in the case of a violation of this subsection other than a violation of paragraph (1) or (2) involving a list I chemical, or both.

(d)(1) Any person who assembles, maintains, places, or causes to be placed a boobytrap on Federal property where a controlled substance is being manufactured, distributed, or dispensed shall be sentenced to a term of imprisonment for not more than 10 years or fined under title 18, United States Code, or both.

(2) If any person commits such a violation after 1 or more prior convictions for an offense punishable under this subsection, such person shall be sentenced to a term of imprisonment of not more than 20 years or fined under title 18, United States Code, or both.

(3) For the purposes of this subsection, the term "boobytrap" means any concealed or camouflaged device designed to cause bodily injury when triggered by any action of any unsuspecting person making contact with the device. Such term includes guns, ammunition, or explosive devices attached to trip wires or other triggering mechanisms, sharpened stakes, and lines or wires with hooks attached.

(e) In addition to any other applicable penalty, any person convicted of a felony violation of this section relating to the receipt, distribution, manufacture, exportation, or importation of a listed chemical may be enjoined from engaging in any transaction involving a listed chemical for not more than ten years.

(f)(1) Whoever knowingly distributes a listed chemical in violation of this title (other than in violation of a recordkeeping or reporting requirement of section 310) shall, except to the extent that paragraph (12), (13), or (14) of section 402(a) applies, be fined under title 18, United States Code, or imprisoned not more than 5 years, or both.

(2) Whoever possesses any listed chemical, with knowledge that the recordkeeping or reporting requirements of section 310 have not been adhered to, if, after such knowledge is acquired, such person does not take immediate steps to remedy the violation shall be fined under title 18, United States Code, or imprisoned not more than one year, or both.

(g) INTERNET SALES OF DATE RAPE DRUGS.—

(1) Whoever knowingly uses the Internet to distribute a date rape drug to any person, knowing or with reasonable cause to believe that—

(A) the drug would be used in the commission of criminal sexual conduct; or

(B) the person is not an authorized purchaser;

shall be fined under this title or imprisoned not more than 20 years, or both.

(2) As used in this subsection:

(A) The term "date rape drug" means—

(i) gamma hydroxybutyric acid (GHB) or any controlled substance analogue of GHB, including gamma butyrolactone (GBL) or 1,4–butanediol;

(ii) ketamine;

(iii) flunitrazepam; or

(iv) any substance which the Attorney General designates, pursuant to the rulemaking procedures prescribed by section 553 of title 5, United States Code, to be used in committing rape or sexual assault.

The Attorney General is authorized to remove any substance from the list of date rape drugs pursuant to the same rulemaking authority.

(B) The term "authorized purchaser" means any of the following persons, provided such person has acquired the controlled substance in accordance with this Act:

(i) A person with a valid prescription that is issued for a legitimate medical purpose in the usual course of professional practice that is based upon a qualifying medical relationship by a practitioner registered by the Attorney General. A "qualifying medical relationship" means a medical relationship that exists when the practitioner has conducted at least 1 medical evaluation with the authorized purchaser in the physical presence of the practitioner, without regard to whether portions of the evaluation are conducted by other heath professionals. The preceding sentence shall not be construed to imply that 1 medical evaluation demonstrates that a prescription has been issued for a legitimate medical purpose within the usual course of professional practice.

(ii) Any practitioner or other registrant who is otherwise authorized by their registration to dispense, pro-

cure, purchase, manufacture, transfer, distribute, import, or export the substance under this Act.

(iii) A person or entity providing documentation that establishes the name, address, and business of the person or entity and which provides a legitimate purpose for using any "date rape drug" for which a prescription is not required.

(3) The Attorney General is authorized to promulgate regulations for record-keeping and reporting by persons handling 1,4–butanediol in order to implement and enforce the provisions of this section. Any record or report required by such regulations shall be considered a record or report required under this Act.

(h) OFFENSES INVOLVING DISPENSING OF CONTROLLED SUBSTANCES BY MEANS OF THE INTERNET.—

(1) IN GENERAL.—It shall be unlawful for any person to knowingly or intentionally—

(A) deliver, distribute, or dispense a controlled substance by means of the Internet, except as authorized by this title; or

(B) aid or abet (as such terms are used in section 2 of title 18, United States Code) any activity described in subparagraph (A) that is not authorized by this title.

(2) EXAMPLES.—Examples of activities that violate paragraph (1) include, but are not limited to, knowingly or intentionally—

(A) delivering, distributing, or dispensing a controlled substance by means of the Internet by an online pharmacy that is not validly registered with a modification authorizing such activity as required by section 303(g) (unless exempt from such registration);

(B) writing a prescription for a controlled substance for the purpose of delivery, distribution, or dispensation by means of the Internet in violation of section 309(e);

(C) serving as an agent, intermediary, or other entity that causes the Internet to be used to bring together a buyer and seller to engage in the dispensing of a controlled substance in a manner not authorized by sections 303(g) or 309(e);

(D) offering to fill a prescription for a controlled substance based solely on a consumer's completion of an online medical questionnaire; and

(E) making a material false, fictitious, or fraudulent statement or representation in a notification or declaration under subsection (d) or (e), respectively, of section 311.

(3) INAPPLICABILITY.—

(A) This subsection does not apply to—

(i) the delivery, distribution, or dispensation of controlled substances by nonpractitioners to the extent authorized by their registration under this title;

(ii) the placement on the Internet of material that merely advocates the use of a controlled substance or includes pricing information without attempting to propose or facilitate an actual transaction involving a controlled substance; or

(iii) except as provided in subparagraph (B), any activity that is limited to—

(I) the provision of a telecommunications service, or of an Internet access service or Internet information location tool (as those terms are defined in section 231 of the Communications Act of 1934); or

(II) the transmission, storage, retrieval, hosting, formatting, or translation (or any combination thereof) of a communication, without selection or alteration of the content of the communication, except that deletion of a particular communication or material made by another person in a manner consistent with section 230(c) of the Communications Act of 1934 shall not constitute such selection or alteration of the content of the communication.

(B) The exceptions under subclauses (I) and (II) of subparagraph (A)(iii) shall not apply to a person acting in concert with a person who violates paragraph (1).

(4) KNOWING OR INTENTIONAL VIOLATION.—Any person who knowingly or intentionally violates this subsection shall be sentenced in accordance with subsection (b).

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CONTROLLED SUBSTANCES IMPORT AND EXPORT ACT

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TITLE III—IMPORTATION AND EXPORTATION; AMENDMENTS AND REPEALS OF REVENUE LAWS

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PART A—IMPORTATION AND EXPORTATION

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PROHIBITED ACTS A—PENALTIES

SEC. 1010. (a) Any person who—

(1) contrary to section 305, 1002, 1003, or 1007, knowingly or intentionally imports or exports a controlled substance,

(2) contrary to section 1005, knowingly or intentionally brings or possesses on board a vessel, aircraft, or vehicle a controlled substance, or

(3) contrary to section 1009, manufactures, possesses with intent to distribute, or distributes a controlled substance,

shall be punished as provided in subsection (b).

(b)(1) In the case of a violation of subsection (a) of this section involving—

(A) 1 kilogram or more of a mixture or substance containing a detectable amount of heroin;

(B) 5 kilograms or more of a mixture or substance containing a detectable amount of—

(i) coca leaves, except coca leaves and extracts of coca leaves from which cocaine, ecgonine, and derivatives of ecgonine or their salts have been removed;

(ii) cocaine, its salts, optical and geometric isomers, and salts or isomers;

(iii) ecgonine, its derivatives, their salts, isomers, and salts of isomers; or

(iv) any compound, mixture, or preparation which contains any quantity of any of the substances referred to in clauses (i) through (iii);

(C) 280 grams or more of a mixture or substance described in subparagraph (B) which contains cocaine base;

(D) 100 grams or more of phencyclidine (PCP) or 1 kilogram or more of a mixture or substance containing a detectable amount of phencyclidine (PCP);

(E) 10 grams or more of a mixture or substance containing a detectable amount of lysergic acid diethylamide (LSD);

(F) 400 grams or more of a mixture or substance containing a detectable amount of N-phenyl-N-[1-(2-phenylethyl)-4-piperidinyl] propanamide or 100 grams or more of a mixture or substance containing a detectable amount of any analogue of N-phenyl-N-[1-(2-phenylethyl)-4-piperidinyl] propanamide *or a fentanyl-related substance*;

(G) 1000 kilograms or more of a mixture or substance containing a detectable amount of marihuana; or

(H) 50 grams or more of methamphetamine, its salts, isomers, and salts of its isomers or 500 grams or more of a mixture or substance containing a detectable amount of methamphetamine, its salts, isomers, or salts of its isomers.

the person committing such violation shall be sentenced to a term of imprisonment of not less than 10 years and not more than life and if death or serious bodily injury results from the use of such substance shall be sentenced to a term of imprisonment of not less than 20 years and not more than life, a fine not to exceed the greater of that authorized in accordance with the provisions of title 18, United States Code, or $10,000,000 if the defendant is an individual or $50,000,000 if the defendant is other than an individual, or both. If any person commits such a violation after a prior conviction for a serious drug felony or serious violent felony has become final, such person shall be sentenced to a term of imprisonment of not less than 15 years and not more than life imprisonment and if death or serious bodily injury results from the use of such substance shall be sentenced to life imprisonment, a fine not to exceed the greater of twice that authorized in accordance with the provisions of title 18, United States Code, or $20,000,000 if the defendant is an individual or $75,000,000 if the defendant is other than an individual, or both. Notwithstanding section 3583 of title 18, any sentence under this paragraph shall, in the absence of such a prior conviction, impose a term of supervised release of at least 5 years in addition to such term of imprisonment and shall, if there was such a prior conviction, impose a term of supervised release of at least 10 years in addition to such term of imprisonment. Notwithstanding any other provision of law, the court shall not place on probation or suspend the sentence of any person sentenced under this paragraph. No person sentenced under this paragraph

shall be eligible for parole during the term of imprisonment imposed therein.

(2) In the case of a violation of subsection (a) of this section involving—

(A) 100 grams or more of a mixture or substance containing a detectable amount of heroin;

(B) 500 grams or more of a mixture or substance containing a detectable amount of—

(i) coca leaves, except coca leaves and extracts of coca leaves from which cocaine, ecgonine, and derivatives of ecgonine or their salts have been removed;

(ii) cocaine, its salts, optical and geometric isomers, and salts or isomers;

(iii) ecgonine, its derivatives, their salts, isomers, and salts of isomers; or

(iv) any compound, mixture, or preparation which contains any quantity of any of the substances referred to in clauses (i) through (iii);

(C) 28 grams or more of a mixture or substance described in subparagraph (B) which contains cocaine base;

(D) 10 grams or more of phencyclidine (PCP) or 100 grams or more of a mixture or substance containing a detectable amount of phencyclidine (PCP);

(E) 1 gram or more of a mixture or substance containing a detectable amount of lysergic acid diethylamide (LSD);

(F) 40 grams or more of a mixture or substance containing a detectable amount of N-phenyl-N-[1-(2-phenylethyl)-4-piperidinyl] propanamide or 10 grams or more of a mixture or substance containing a detectable amount of any analogue of N-phenyl-N-[1-(2-phenylethyl)-4-piperidinyl] propanamide *or a fentanyl-related substance*;

(G) 100 kilograms or more of a mixture or substance containing a detectable amount of marihuana; or

(H) 5 grams or more of methamphetamine, its salts, isomers, and salts of its isomers or 50 grams or more of a mixture or substance containing a detectable amount of methamphetamine, its salts, isomers, or salts of its isomers.

the person committing such violation shall be sentenced to a term of imprisonment of not less than 5 years and not more than 40 years and if death or serious bodily injury results from the use of such substance shall be sentenced to a term of imprisonment of not less than twenty years and not more than life, a fine not to exceed the greater of that authorized in accordance with the provisions of title 18, United States Code, or $5,000,000 if the defendant is an individual or $25,000,000 if the defendant is other than an individual, or both. If any person commits such a violation after a prior conviction for a serious drug felony or serious violent felony has become final, such person shall be sentenced to a term of imprisonment of not less than 10 years and not more than life imprisonment and if death or serious bodily injury results from the use of such substance shall be sentenced to life imprisonment, a fine not to exceed the greater of twice that authorized in accordance with the provisions of title 18, United States Code, or $8,000,000 if the defendant is an individual or $50,000,000 if the defendant is other than an individual, or both. Notwithstanding section 3583 of title

18, any sentence imposed under this paragraph shall, in the absence of such a prior conviction, include a term of supervised release of at least 4 years in addition to such term of imprisonment and shall, if there was such a prior conviction, include a term of supervised release of at least 8 years in addition to such term of imprisonment. Notwithstanding any other provision of law, the court shall not place on probation or suspend the sentence of any person sentenced under this paragraph. No person sentenced under this paragraph shall be eligible for parole during the term of imprisonment imposed therein.

(3) In the case of a violation under subsection (a) of this section involving a controlled substance in schedule I or II, gamma hydroxybutyric acid (including when scheduled as an approved drug product for purposes of section 3(a)(1)(B) of the Hillory J. Farias and Samantha Reid Date-Rape Drug Prohibition Act of 2000), or flunitrazepam, the person committing such violation shall, except as provided in paragraphs (1), (2), and (4), be sentenced to a term of imprisonment of not more than 20 years and if death or serious bodily injury results from the use of such substance shall be sentenced to a term of imprisonment of not less than twenty years and not more than life, a fine not to exceed the greater of that authorized in accordance with the provisions of title 18, United States Code, or $1,000,000 if the defendant is an individual or $5,000,000 if the defendant is other than an individual, or both. If any person commits such a violation after a prior conviction for a felony drug offense has become final, such person shall be sentenced to a term of imprisonment of not more than 30 years and if death or serious bodily injury results from the use of such substance shall be sentenced to life imprisonment, a fine not to exceed the greater of twice that authorized in accordance with the provisions of title 18, United States Code, or $2,000,000 if the defendant is an individual or $10,000,000 if the defendant is other than an individual, or both. Notwithstanding section 3583 of title 18, any sentence imposing a term of imprisonment under this paragraph shall, in the absence of such a prior conviction, impose a term of suspervised release of at least 3 years in addition to such term of imprisonment and shall, if there was such a prior conviction, impose a term of suspervised release of at least 6 years in addition to such term of imprisonment. Notwithstanding the prior sentence, and notwithstanding any other provision of law, the court shall not place on probation or suspend the sentence of any person sentenced under the provisions of this paragraph which provide for a mandatory term of imprisonment if death or serious bodily injury results.

(4) In the case of a violation under subsection (a) with respect to less than 50 kilograms of marihuana except in the case of 100 or more marihuana plants regardless of weight, less than 10 kilograms of hashish, or less than one kilogram of hashish oil, the person committing such violation shall be sentenced in accordance with section 401(b)(1)(D).

(5) In the case of a violation of subsection (a) involving a controlled substance in schedule III, such person shall be sentenced in accordance with section 401(b)(1).

(6) In the case of a violation of subsection (a) involving a controlled substance in schedule IV, such person shall be sentenced in accordance with section 401(b)(2).

(7) In the case of a violation of subsection (a) involving a controlled substance in schedule V, such person shall be sentenced in accordance with section 401(b)(3).

(c) A special parole term imposed under this section or section 1012 may be revoked if its terms and conditions are violated. In such circumstances the original term of imprisonment shall be increased by the period of the special parole term and the resulting new term of imprisonment shall not be diminished by the time which was spent on special parole. A person whose special parole term has been revoked may be required to serve all or part of the remainder of the new term of imprisonment. The special term provided for in this section and in section 1012 is in addition to, and not in lieu of, any other parole provided for by law.

(d) A person who knowingly or intentionally—

(1) imports or exports a listed chemical with intent to manufacture a controlled substance in violation of this title or title II;

(2) exports a listed chemical in violation of the laws of the country to which the chemical is exported or serves as a broker or trader for an international transaction involving a listed chemical, if the transaction is in violation of the laws of the country to which the chemical is exported;

(3) imports or exports a listed chemical knowing, or having reasonable cause to believe, that the chemical will be used to manufacture a controlled substance in violation of this title or title II;

(4) exports a listed chemical, or serves as a broker or trader for an international transaction involving a listed chemical, knowing, or having reasonable cause to believe, that the chemical will be used to manufacture a controlled substance in violation of the laws of the country to which the chemical is exported;

(5) imports or exports a listed chemical, with the intent to evade the reporting or recordkeeping requirements of section 1018 applicable to such importation or exportation by falsely representing to the Attorney General that the importation or exportation qualifies for a waiver of the 15-day notification requirement granted pursuant to paragraph (2) or (3) of section 1018(f) by misrepresenting the actual country of final destination of the listed chemical or the actual listed chemical being imported or exported;

(6) imports a listed chemical in violation of section 1002, imports or exports such a chemical in violation of section 1007 or 1018, or transfers such a chemical in violation of section 1018(d); or

(7) manufactures, possesses with intent to distribute, or distributes a listed chemical in violation of section 959 of this title.

shall be fined in accordance with title 18, imprisoned not more than 20 years in the case of a violation of paragraph (1) or (3) involving a list I chemical or not more than 10 years in the case of a violation of this subsection other than a violation of paragraph (1) or (3) involving a list I chemical, or both.

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MINORITY VIEWS

H.R. 467, the HALT Fentanyl Act, fails to take a comprehensive approach to addressing fentanyl-related substances and the broader fentanyl crisis.

In 2018, the Drug Enforcement Administration (DEA) used emergency authority under the Controlled Substances Act (CSA) to temporarily place fentanyl-related substances (FRS) in Schedule I as a class, based on chemical structure. Schedule I is reserved for drugs deemed to have no accepted medical use, a high potential for abuse, and a lack of accepted safety, and the CSA prohibits the manufacture, distribution, dispensation, and possession of Schedule I substances except for federal government-approved research studies. This emergency action was set to expire two years after implementation.

Congress has voted eight times to extend temporary class-wide FRS scheduling. Once in 2020, three times in 2021, and four times in 2022. Most recently, Congress extended the temporary class-wide scheduling order in the FY 23 Consolidated Appropriations Act to December 31, 2024.

In September 2021, the Biden Administration released a proposal to address FRS, which formally recommended permanent class-wide scheduling FRS, along with other comprehensive guardrails. The Administration's legislative proposal to permanently address FRS was an interagency agreement made by ONDCP, HHS, which includes FDA and NIH, and DOJ, which includes DEA. DEA is supportive of this interagency proposal. Among multiple provisions, the proposal would:

- Permanently place all FRS into Schedule I based on chemical structure, except those FRS specifically exempted or listed in another schedule.
- Exclude FRS from quantity based mandatory minimums, unless an offense results in serious bodily injury or death. Offenders would instead be subject to DOJ sentencing guidelines.
- Create an "off-ramp" for FRS, an expedited process to remove or reschedule FRS that are found not to belong in schedule I or II. The Administration acknowledges that some FRS may have no pharmacological effect and not pose a threat to public health because chemical structure alone does not determine pharmacological effect. Yet, FRS will be preemptively placed in the most restrictive class. The off ramp would allow the Administration to act swiftly to reschedule or deschedule a substance if it is found to pose no harm or have clinical benefit.
- Enable sentences of individuals convicted of an offense involving an FRS that is subsequently removed or rescheduled to be reduced or vacated.

- Simplify the research registration process for schedule I substances, aligning them closer to the process for schedule II. Applies to investigators funded by HHS, VA, or under an lnvestigational New Drug (IND) Exemption from the FDA.
- Require a GAO report analyzing the implementation and impact of permanent FRS class scheduling, including analysis of impact on research, removal and rescheduling actions, effect on illicit manufacturing and trafficking, proliferation of new FRS, and sentencing outcomes.

H.R. 467, the HALT Fentanyl Act, includes only two of the Administration's recommendations, the requirement to permanently schedule FRS and the provisions that streamline research registration requirements. Further, the bill, as amended during the mark-up process, expands mandatory minimum sentencing, a step that the Administration did not recommend. The majority rejected all Democratic amendments to this bill, including an amendment to implement the Biden Administration's interagency proposal to permanently schedule fentanyl-related substances.

The bill, as amended and passed by the full committee, does little to comprehensively address the fentanyl crisis, as it fails to expand treatment, reduce demand, or raise public awareness of the dangers of fentanyl, but rather takes an incarcerate first approach that is not evidence-based. As such, there are strong concerns that its provisions will not lead to a meaningful reduction in overdose deaths involving fentanyl.

FRANK PALLONE, Jr.,
Ranking Member.

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