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115TH CONGRESS
1ST SESSION

H. R. 1781

To improve the ability of the Federal Government to address synthetic opioids, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

MARCH 29, 2017

Mr. DONOVAN (for himself and Mr. THOMAS J. ROONEY of Florida) introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committees on the Judiciary, and Oversight and Government Reform, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

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A BILL

To improve the ability of the Federal Government to address synthetic opioids, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE; TABLE OF CONTENTS.

(a) SHORT TITLE.—This Act may be cited as the ''Comprehensive Fentanyl Control Act''.

(b) TABLE OF CONTENTS.—The table of contents of this Act is as follows:

SEC. 2. FINDINGS; SENSE OF CONGRESS.

(a) FINDINGS.—The Congress finds as follows:

(1) Fentanyl is a dangerous, synthetic opioid that's 50 to 100 times more potent than heroin and morphine and lethal in doses as small as approximately 2 milligrams. Current sentencing enhancements do not reflect the danger fentanyl poses at lower quantities compared to other illicit substances.

(2) Because a lethal dose of fentanyl can be accidentally inhaled or absorbed through the skin, it's not just deadly to its users, but it also threatens the lives of law enforcement and customs officials, public health workers, first responders and postal workers who risk unknowingly coming into contact with fentanyl in its different forms.

(3) From 2013 to 2014, the number of drug seizures by law enforcement that tested positive for fentanyl increased by 426 percent and synthetic opioid-related deaths increased by 79 percent, with over 700 overdose deaths related to fentanyl. However, due to variations in States' medical examiner and coroner testing and reporting techniques, and

deaths attributed to heroin, this figure is believed to be significantly higher.

(4) Illicitly manufactured fentanyl, pill press machines, and other supplies needed to manufacture counterfeit pills containing fentanyl are primarily sourced from China and widely available for purchase on the Internet. Traffickers can typically purchase a kilogram of fentanyl powder for as little as $2,000 from a Chinese supplier, transform it into hundreds of thousands of pills, and sell the counterfeit pills for millions of dollars in profit.

(5) In 2015, the Drug Enforcement Administration (DEA) and Centers for Disease Control and Prevention (CDC) issued nationwide alerts identifying fentanyl as a threat to public health and safety and stating that the rise of counterfeit pills that contain fentanyl in the illicit drug market will likely result in more opioid-dependent individuals, overdoses, and deaths.

(6) The DEA has identified two key challenges for using the Controlled Substances Analogue Enforcement Act of 1986 (21 U.S.C. 801 note) to prosecute individuals for violations relating to fentanyl:

(A) The law requires that the substance have a substantially similar chemical structure

to a controlled substance in order to be considered an analogue, yet the threshold for ''substantially similar'' has been cited by numerous courts as difficult to apply.

(B) Each case requires additional investigation to determine whether the substance in question was ''intended for human consumption'' and can therefore be considered an analogue.

(7) Illicit fentanyl manufacturers are continuously manipulating the chemical structures of the analogues in order to stay ahead of researchers and law enforcement, thus making prosecuting these crimes overly onerous. Furthermore, the speed at which these alterations can be made outpace the current authorities of the Department of Justice to schedule new compounds and analogues under the Controlled Substances Act (21 U.S.C. 801 et seq.).

(b) SENSE OF CONGRESS.—It is the sense of the Congress that—

(1) the trafficking in fentanyl and other synthetic opioids represents a public health emergency in the United States and requires a comprehensive legislative response;

(2) the United States Government should use all available measures to reduce the availability of illicit fentanyl, its chemical precursors, and the equipment by which fentanyl may be milled into counterfeit prescription pills;

(3) the United States Government should make grants available for State and local medical examiners and coroners to screen for fentanyl in suspected opioid overdose cases in regions reporting increases in fentanyl seizures, fentanyl-related overdose fatalities, or unusually high spikes in heroin or unspecified drug overdose fatalities;

(4) State and local law enforcement should, if safe and possible, prioritize and expedite testing of drug samples taken from drug overdose scenes and share the data on fentanyl drug seizures with local health departments, coroners, and medical examiners;

(5) grants made available to address the opioid epidemic should be used to improve States' surveillance of fentanyl-related deaths and to expand access to naloxone for first responders, law enforcement, and health care personnel given that multiple doses of naloxone must be administered per overdose event; and

(6) the United States Government, including the Secretary of State, the Attorney General, the Secretary of Homeland Security, and the Director of the Office of National Drug Control Policy, should use the broad diplomatic and law enforcement resources of the United States, in partnership with the Governments of Mexico and China, to stop the trafficking of illicit fentanyl into the United States.

SEC. 3. ENHANCED PENALTIES.

(a) CONTROLLED SUBSTANCES ACT AMENDMENTS.—The Controlled Substances Act is amended—

(1) in section 401(b)(1) (21 U.S.C. 841(b)(1))—

(A) in subparagraph (A)(vi)—

(i) by striking ''400 grams'' and inserting ''20 grams''; and

(ii) by striking ''100 grams'' and inserting ''5 grams''; and

(B) in subparagraph (B)(vi)—

(i) by striking ''40 grams'' and inserting ''2 grams''; and

(ii) by striking ''10 grams'' and inserting ''0.5 grams''; and

(2) by adding at the end of section 401(b) (21 U.S.C. 841(b)) the following:

''(8) In the case of a violation of subsection (a), if the mixture or substance contains a detectable amount of N-phenyl-[1–(2-phenylethyl)–4-piperidinyl] propanamide or any analogue of N-phenyl-[1–(2-phenylethyl)–4-piperidinyl] propanamide and also contains a detectable amount of another controlled substance, then a court shall—

''(A) not impose a term of probation;

''(B) in addition to the term of punishment for the violation of this section, impose a term of imprisonment not to exceed 5 years; and

''(C) no term of imprisonment imposed on a person under subparagraph (B) shall run concurrently with any term of imprisonment imposed on the person under any other provision of law.

''(9) In the case of a violation of subsection (a), if the mixture or substance containing a detectable amount of N-phenyl-[1–(2-phenylethyl)–4-piperidinyl] propanamide or any analogue of N-phenyl-[1–(2-phenylethyl)–4-piperidinyl] propanamide was represented to be or sold as another controlled substance, then a court shall—

''(A) not impose a term of probation;

''(B) in addition to the term of punishment for the violation of this section, impose a term of imprisonment not to exceed 5 years; and

''(C) no term of imprisonment imposed on a person under subparagraph (B) shall run concurrently with any term of imprisonment imposed on the person under any other provision of law.''.

(b) CONTROLLED SUBSTANCES IMPORT AND EXPORT ACT AMENDMENTS.—Section 1010(b) of the Controlled Substances Import and Export Act (21 U.S.C. 960(b)) is amended by adding at the end the following:

''(8) In the case of a violation of subsection (a), if the mixture or substance containing a detectable amount of N-phenyl-[1–(2-phenylethyl)–4-piperidinyl] propanamide or any analogue of N-phenyl-[1–(2-phenylethyl)–4-piperidinyl] propanamide also contains a detectable amount of another controlled substance, then a court shall—

''(A) not impose a term of probation;

''(B) in addition to the term of punishment for the violation of this section, impose a term of imprisonment not to exceed 5 years; and

''(C) no term of imprisonment imposed on a person under subparagraph (B) shall run con-

currently with any term of imprisonment imposed on the person under any other provision of law.

''(9) In the case of a violation of subsection (a), if the mixture or substance containing a detectable amount of N-phenyl-[1–(2-phenylethyl)–4-piperidinyl] propanamide or any analogue of N-phenyl-[1–(2-phenylethyl)–4-piperidinyl] propanamide was represented to be or sold as another controlled substance, then a court shall—

''(A) not impose a term of probation;

''(B) in addition to the term of punishment for the violation of this section, impose a term of imprisonment not to exceed 5 years; and

''(C) no term of imprisonment imposed on a person under subparagraph (B) shall run concurrently with any term of imprisonment imposed on the person under any other provision of law.''.

SEC. 4. ENDANGERING HUMAN LIFE WHILE ILLEGALLY MANUFACTURING CONTROLLED SUBSTANCE.

Section 417 of the Controlled Substances Act (21 U.S.C. 858) is amended to read as follows:

"SEC. 417. ENDANGERING HUMAN LIFE WHILE ILLEGALLY MANUFACTURING CONTROLLED SUBSTANCE.

''(a) IN GENERAL.—Whoever, while manufacturing a controlled substance in violation of this title, or attempting to do so, or transporting or causing to be transported materials, including chemicals, to do so, creates a substantial risk of harm to human life shall be fined in accordance with title 18, United States Code, or imprisoned not more than 10 years, or both.

''(b) REBUTTABLE PRESUMPTION.—For purposes of this section, there shall be rebuttable presumption that any violation of subsection (a) involving a detectable amount of N-phenyl-[1–(2-phenylethyl)–4-piperidinyl] propanamide, any analogue of N-phenyl-[1–(2-phenylethyl)–4-piperidinyl] propanamide, or the immediate precursor of such a substance, creates a substantial risk of harm to human life.''.

SEC. 5. TEMPORARY SCHEDULING OF SYNTHETIC OPIOIDS.

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

''(k) TEMPORARY AND PERMANENT SCHEDULING OF RECENTLY EMERGED SYNTHETIC OPIOIDS.—

''(1) IN GENERAL.—The Attorney General may issue a temporary order adding a drug or other sub-

stance to the definition of synthetic opioids if the Attorney General finds that—

"(A) the drug or other substance satisfies the criteria for being considered a synthetic opioid but is not listed in that section or by regulation of the Attorney General as being a synthetic opioid; and

"(B) adding such drug or other substance to the definition of synthetic opioids will assist in preventing abuse or misuse of the drug or other substance.

"(2) EFFECTIVE DATE; DURATION.—An order issued under paragraph (1) shall not take effect until 30 days after the date of the publication by the Attorney General of a notice in the Federal Register of the intention to issue such order and the grounds upon which such order is to be issued. The order shall expire not later than 24 months after the date it becomes effective, except that the Attorney General may, during the pendency of proceedings under paragraph (6), extend the temporary scheduling order for up to 6 months.

"(3) NOTICE.—The Attorney General shall transmit notice of an order proposed to be issued under paragraph (1) to the Secretary of Health and

Human Services. In issuing an order under paragraph (1), the Attorney General shall take into consideration any comments submitted by the Secretary in response to a notice transmitted pursuant to this paragraph.

''(4) EFFECT OF PERMANENT SCHEDULING.—A temporary scheduling order issued under paragraph (1) shall be vacated upon the issuance of a permanent scheduling order under paragraph (6).

''(5) JUDICIAL REVIEW.—An order issued under paragraph (1) is not subject to judicial review.

''(6) PERMANENT SCHEDULING.—The Attorney General may, by rule, issue a permanent order adding a drug or other substance to the definition of synthetic opioids if such drug or other substance satisfies the criteria for being considered a synthetic opioid. Such rulemaking may be commenced simultaneously with the issuance of the temporary order issued under paragraph (1).''.

SEC. 6. TABLETING MACHINES, ENCAPSULATING MACHINES, AND CONTROLLED SUBSTANCE COUNTERFEITING MATERIALS.

(a) MAILABILITY.—

(1) IN GENERAL.—Chapter 30 of title 39, United States Code, is amended by inserting after section 3002a, the following new section:

"§ 3002b. Nonmailability of tableting machines, encapsulating machines, and controlled substance counterfeiting materials

''(a) Any tableting machine, encapsulating machine, or controlled substance counterfeiting material is nonmailable matter, shall not be carried or delivered by mail, and shall be disposed of as the Postal Service directs, unless such device or material is mailed—

''(1) to a regulated person (as defined in section 102(38) of the Controlled Substances Act); or

''(2) to a person registered to manufacture a controlled substance by the Attorney General pursuant to section 302 of the Controlled Substances Act.

''(b) For the purpose of this section—

''(1) the term 'controlled substance counterfeiting material' means any punch, die, plate, stone, or other thing described section 403(a)(5) of the Controlled Substances Act;

''(2) the term 'encapsulating machine' means any manual, semiautomatic, or fully automatic equipment which may be used to fill shells or cap-

sules with any powdered, granular, semisolid, or liquid material; and

''(3) the term 'tableting machine' means any manual, semiautomatic, or fully automatic equipment which may be used for the compaction or molding of powdered or granular solids, or semisolid material, to produce coherent solid tablets.''.

(2) CLERICAL AMENDMENT.—The table of sections for chapter 30 of title 39, United States Code, is amended by inserting after the item relating to section 3002a the following new item:

''3002b. Nonmailability of tableting machines, encapsulating machines, and controlled substance counterfeiting materials.''.

(b) PENALTY.—

(1) IN GENERAL.—Chapter 83 of title 18, United States Code, is amended by inserting after section 1716E the following new section:

''§ 1716F. Nonmailability of tableting machines, encapsulating machines, and controlled substance counterfeiting materials

''Whoever knowingly deposits for mailing or delivery, or knowingly causes to be delivered by mail according to the direction thereon, or at any place to which it is directed to be delivered by the person to whom it is addressed, any matter declared to be nonmailable by section

3002c of title 39, shall be fined under this title or imprisoned not more than 1 year, or both.''.

(2) CLERICAL AMENDMENT.—The table of sections for chapter 83 of title 18, United States Code, is amended by inserting after the item relating to section 1716E the following new item:

''1716F. Nonmailability of tableting machines, encapsulating machines, and controlled substance counterfeiting materials.''.

SEC. 7. LABELING REQUIREMENTS.

(a) IN GENERAL.—Section 305 of the Controlled Substances Act (21 U.S.C. 825) is amended by adding at the end the following:

''(f) FALSE LABELING OF SYNTHETIC OPIOIDS.—

''(1) It shall be unlawful to import, export, manufacture, distribute, dispense, or possess with intent to manufacture, distribute, or dispense, a synthetic opioid or product containing a synthetic opioid, unless the opioid or product bears a label clearly identifying a synthetic opioid or product containing a synthetic opioid by the nomenclature used by the International Union of Pure and Applied Chemistry (IUPAC).

''(2)(A) A product described in subparagraph (B) is exempt from the International Union of Pure and Applied Chemistry nomenclature requirement of this subsection if such product is labeled in the man-

ner required under the Federal Food, Drug, and Cosmetic Act.

''(B) A product is described in this subparagraph if the product—

''(i) is the subject of an approved application as described in section 505(b) or (j) of the Federal Food, Drug, and Cosmetic Act; or

''(ii) is exempt from the provisions of section 505 of such Act relating to new drugs because—

''(I) it is intended solely for investigational use as described in section 505(i) of such Act; and

''(II) such product is being used exclusively for purposes of a clinical trial that is the subject of an effective investigational new drug application.''.

(b) CLARIFICATION TO IMPORT AND EXPORT STATUTE.—Section 1010 of the Controlled Substances Import and Export Act (21 U.S.C. 960) is amended, in subsection (a)(1), by inserting ''305,'' before ''1002''.

(c) CIVIL PENALTIES.—Section 402 of the Controlled Substances Act (21 U.S.C. 842) is amended—

(1) in subsection (a)—

(A) in paragraph (15), by striking ''or'' at the end;

(B) in paragraph (16), by striking the period at the end and inserting ''; or''; and

(C) by inserting, after paragraph (16), the following:

''(17) to violate subsection (f) of section 825 of this title.''; and

(2) in subsection (c)(1)—

(A) by inserting, in subparagraph (A), after ''subparagraph (B), (C),'' striking ''or (D)'' and inserting the following: '', (D), (E), or (F)''; and

(B) by inserting after subparagraph (D) the following:

''(E) In the case of a violation of paragraph (17) of subsection (a) of this section by an importer, exporter, manufacturer, or distributor (other than as provided in subparagraph (F)), up to $500,000 per violation. For purposes of this subparagraph, a violation is defined as each instance of importation, exportation, manufacturing, distribution, or possession with intent to manufacture or distribute, in violation of paragraph (17) of subsection (a).

''(F) In the case of a distribution, dispensing, or possession with intent to distribute or dispense in violation

of paragraph (17) of subsection (a) of this section at the retail level, up to $1,000 per violation. Each package, container or other separate unit containing a synthetic opioid that is distributed, dispensed, or possessed with intent to distribute or dispense at the retail level in violation of such paragraph (17) of subsection (a) shall be considered a separate violation.''.

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