

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

A BILL

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

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE; TABLE OF CONTENTS.**

4 (a) SHORT TITLE.—This Act may be cited as the
5 “Comprehensive Fentanyl Control Act”.

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

- Sec. 1. Short title; table of contents.
- Sec. 2. Findings; sense of Congress.
- Sec. 3. Enhanced penalties.

Sec. 4. Endangering human life while illegally manufacturing controlled substance.

Sec. 5. Temporary scheduling of synthetic opioids.

Sec. 6. Tableting machines, encapsulating machines, and controlled substance counterfeiting materials.

Sec. 7. Labeling requirements.

1 **SEC. 2. FINDINGS; SENSE OF CONGRESS.**

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

3 (1) Fentanyl is a dangerous, synthetic opioid
4 that's 50 to 100 times more potent than heroin and
5 morphine and lethal in doses as small as approxi-
6 mately 2 milligrams. Current sentencing enhance-
7 ments do not reflect the danger fentanyl poses at
8 lower quantities compared to other illicit substances.

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

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

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

3 (4) Illicitly manufactured fentanyl, pill press
4 machines, and other supplies needed to manufacture
5 counterfeit pills containing fentanyl are primarily
6 sourced from China and widely available for pur-
7 chase on the Internet. Traffickers can typically pur-
8 chase a kilogram of fentanyl powder for as little as
9 \$2,000 from a Chinese supplier, transform it into
10 hundreds of thousands of pills, and sell the counter-
11 feit pills for millions of dollars in profit.

12 (5) In 2015, the Drug Enforcement Adminis-
13 tration (DEA) and Centers for Disease Control and
14 Prevention (CDC) issued nationwide alerts identi-
15 fying fentanyl as a threat to public health and safety
16 and stating that the rise of counterfeit pills that
17 contain fentanyl in the illicit drug market will likely
18 result in more opioid-dependent individuals,
19 overdoses, and deaths.

20 (6) The DEA has identified two key challenges
21 for using the Controlled Substances Analogue En-
22 forcement Act of 1986 (21 U.S.C. 801 note) to pros-
23 ecute individuals for violations relating to fentanyl:

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

1 to a controlled substance in order to be consid-
2 ered an analogue, yet the threshold for “sub-
3 stantially similar” has been cited by numerous
4 courts as difficult to apply.

5 (B) Each case requires additional inves-
6 tigation to determine whether the substance in
7 question was “intended for human consump-
8 tion” and can therefore be considered an ana-
9 logue.

10 (7) Illicit fentanyl manufacturers are continu-
11 ously manipulating the chemical structures of the
12 analogues in order to stay ahead of researchers and
13 law enforcement, thus making prosecuting these
14 crimes overly onerous. Furthermore, the speed at
15 which these alterations can be made outpace the cur-
16 rent authorities of the Department of Justice to
17 schedule new compounds and analogues under the
18 Controlled Substances Act (21 U.S.C. 801 et seq.).

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

21 (1) the trafficking in fentanyl and other syn-
22 thetic opioids represents a public health emergency
23 in the United States and requires a comprehensive
24 legislative response;

1 (2) the United States Government should use
2 all available measures to reduce the availability of il-
3 licit fentanyl, its chemical precursors, and the equip-
4 ment by which fentanyl may be milled into counter-
5 feit prescription pills;

6 (3) the United States Government should make
7 grants available for State and local medical exam-
8 iners and coroners to screen for fentanyl in sus-
9 pected opioid overdose cases in regions reporting in-
10 creases in fentanyl seizures, fentanyl-related over-
11 dose fatalities, or unusually high spikes in heroin or
12 unspecified drug overdose fatalities;

13 (4) State and local law enforcement should, if
14 safe and possible, prioritize and expedite testing of
15 drug samples taken from drug overdose scenes and
16 share the data on fentanyl drug seizures with local
17 health departments, coroners, and medical exam-
18 iners;

19 (5) grants made available to address the opioid
20 epidemic should be used to improve States' surveil-
21 lance of fentanyl-related deaths and to expand ac-
22 cess to naloxone for first responders, law enforce-
23 ment, and health care personnel given that multiple
24 doses of naloxone must be administered per overdose
25 event; and

1 (6) the United States Government, including
2 the Secretary of State, the Attorney General, the
3 Secretary of Homeland Security, and the Director of
4 the Office of National Drug Control Policy, should
5 use the broad diplomatic and law enforcement re-
6 sources of the United States, in partnership with the
7 Governments of Mexico and China, to stop the traf-
8 ficking of illicit fentanyl into the United States.

9 **SEC. 3. ENHANCED PENALTIES.**

10 (a) CONTROLLED SUBSTANCES ACT AMEND-
11 MENTS.—The Controlled Substances Act is amended—

12 (1) in section 401(b)(1) (21 U.S.C.
13 841(b)(1))—

14 (A) in subparagraph (A)(vi)—

15 (i) by striking “400 grams” and in-
16 serting “20 grams”; and

17 (ii) by striking “100 grams” and in-
18 serting “5 grams”; and

19 (B) in subparagraph (B)(vi)—

20 (i) by striking “40 grams” and insert-
21 ing “2 grams”; and

22 (ii) by striking “10 grams” and in-
23 serting “0.5 grams”; and

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

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

8 “(A) not impose a term of probation;

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

12 “(C) no term of imprisonment imposed on
13 a person under subparagraph (B) shall run con-
14 currently with any term of imprisonment im-
15 posed on the person under any other provision
16 of law.

17 “(9) In the case of a violation of subsection (a),
18 if the mixture or substance containing a detectable
19 amount of N-phenyl-[1-(2-phenylethyl)-4-
20 piperidinyl] propanamide or any analogue of N-
21 phenyl-[1-(2-phenylethyl)-4-piperidinyl]
22 propanamide was represented to be or sold as an-
23 other controlled substance, then a court shall—

24 “(A) not impose a term of probation;

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

4 “(C) no term of imprisonment imposed on
5 a person under subparagraph (B) shall run con-
6 currently with any term of imprisonment im-
7 posed on the person under any other provision
8 of law.”.

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

13 “(8) In the case of a violation of subsection (a),
14 if the mixture or substance containing a detectable
15 amount of N-phenyl-[1-(2-phenylethyl)-4-
16 piperidinyl] propanamide or any analogue of N-
17 phenyl-[1-(2-phenylethyl)-4-piperidinyl]
18 propanamide also contains a detectable amount of
19 another controlled substance, then a court shall—

20 “(A) not impose a term of probation;

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

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

1 currently with any term of imprisonment im-
2 posed on the person under any other provision
3 of law.

4 “(9) In the case of a violation of subsection (a),
5 if the mixture or substance containing a detectable
6 amount of N-phenyl-[1-(2-phenylethyl)-4-
7 piperidinyl] propanamide or any analogue of N-
8 phenyl-[1-(2-phenylethyl)-4-piperidinyl]
9 propanamide was represented to be or sold as an-
10 other controlled substance, then a court shall—

11 “(A) not impose a term of probation;

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

15 “(C) no term of imprisonment imposed on
16 a person under subparagraph (B) shall run con-
17 currently with any term of imprisonment im-
18 posed on the person under any other provision
19 of law.”.

20 **SEC. 4. ENDANGERING HUMAN LIFE WHILE ILLEGALLY**
21 **MANUFACTURING CONTROLLED SUBSTANCE.**

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

1 **“SEC. 417. ENDANGERING HUMAN LIFE WHILE ILLEGALLY**
2 **MANUFACTURING CONTROLLED SUBSTANCE.**

3 “(a) IN GENERAL.—Whoever, while manufacturing a
4 controlled substance in violation of this title, or attempting
5 to do so, or transporting or causing to be transported ma-
6 terials, including chemicals, to do so, creates a substantial
7 risk of harm to human life shall be fined in accordance
8 with title 18, United States Code, or imprisoned not more
9 than 10 years, or both.

10 “(b) REBUTTABLE PRESUMPTION.—For purposes of
11 this section, there shall be rebuttable presumption that
12 any violation of subsection (a) involving a detectable
13 amount of N-phenyl-[1-(2-phenylethyl)-4-piperidinyl]
14 propanamide, any analogue of N-phenyl-[1-(2-
15 phenylethyl)-4-piperidinyl] propanamide, or the imme-
16 diate precursor of such a substance, creates a substantial
17 risk of harm to human life.”

18 **SEC. 5. TEMPORARY SCHEDULING OF SYNTHETIC OPIOIDS.**

19 Section 201 of the Controlled Substances Act (21
20 U.S.C. 811) is amended by adding at the end the fol-
21 lowing:

22 “(k) TEMPORARY AND PERMANENT SCHEDULING OF
23 RECENTLY EMERGED SYNTHETIC OPIOIDS.—

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

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

3 “(A) the drug or other substance satisfies
4 the criteria for being considered a synthetic
5 opioid but is not listed in that section or by reg-
6 ulation of the Attorney General as being a syn-
7 thetic opioid; and

8 “(B) adding such drug or other substance
9 to the definition of synthetic opioids will assist
10 in preventing abuse or misuse of the drug or
11 other substance.

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

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

1 Human Services. In issuing an order under para-
2 graph (1), the Attorney General shall take into con-
3 sideration any comments submitted by the Secretary
4 in response to a notice transmitted pursuant to this
5 paragraph.

6 “(4) EFFECT OF PERMANENT SCHEDULING.—A
7 temporary scheduling order issued under paragraph
8 (1) shall be vacated upon the issuance of a perma-
9 nent scheduling order under paragraph (6).

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

12 “(6) PERMANENT SCHEDULING.—The Attorney
13 General may, by rule, issue a permanent order add-
14 ing a drug or other substance to the definition of
15 synthetic opioids if such drug or other substance
16 satisfies the criteria for being considered a synthetic
17 opioid. Such rulemaking may be commenced simulta-
18 neously with the issuance of the temporary order
19 issued under paragraph (1).”.

20 **SEC. 6. TABLETING MACHINES, ENCAPSULATING MA-**
21 **CHINES, AND CONTROLLED SUBSTANCE**
22 **COUNTERFEITING MATERIALS.**

23 (a) MAILABILITY.—

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

4 **“§ 3002b. Nonmailability of tableting machines, en-**
5 **capsulating machines, and controlled**
6 **substance counterfeiting materials**

7 “(a) Any tableting machine, encapsulating machine,
8 or controlled substance counterfeiting material is non-
9 mailable matter, shall not be carried or delivered by mail,
10 and shall be disposed of as the Postal Service directs, un-
11 less such device or material is mailed—

12 “(1) to a regulated person (as defined in section
13 102(38) of the Controlled Substances Act); or

14 “(2) to a person registered to manufacture a
15 controlled substance by the Attorney General pursu-
16 ant to section 302 of the Controlled Substances Act.

17 “(b) For the purpose of this section—

18 “(1) the term ‘controlled substance counter-
19 feiting material’ means any punch, die, plate, stone,
20 or other thing described section 403(a)(5) of the
21 Controlled Substances Act;

22 “(2) the term ‘encapsulating machine’ means
23 any manual, semiautomatic, or fully automatic
24 equipment which may be used to fill shells or cap-

1 sules with any powdered, granular, semisolid, or liq-
2 uid material; and

3 “(3) the term ‘tableting machine’ means any
4 manual, semiautomatic, or fully automatic equip-
5 ment which may be used for the compaction or
6 molding of powdered or granular solids, or semisolid
7 material, to produce coherent solid tablets.”.

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

 “3002b. Nonmailability of tableting machines, encapsulating machines, and con-
 trolled substance counterfeiting materials.”.

12 (b) PENALTY.—

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

16 **“§ 1716F. Nonmailability of tableting machines, en-**
17 **capsulating machines, and controlled**
18 **substance counterfeiting materials**

19 “Whoever knowingly deposits for mailing or delivery,
20 or knowingly causes to be delivered by mail according to
21 the direction thereon, or at any place to which it is di-
22 rected to be delivered by the person to whom it is ad-
23 dressed, any matter declared to be nonmailable by section

1 3002c of title 39, shall be fined under this title or impris-
2 oned not more than 1 year, or both.”.

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

“1716F. Nonmailability of tableting machines, encapsulating machines, and con-
trolled substance counterfeiting materials.”.

7 **SEC. 7. LABELING REQUIREMENTS.**

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

11 “(f) FALSE LABELING OF SYNTHETIC OPIOIDS.—

12 “(1) It shall be unlawful to import, export,
13 manufacture, distribute, dispense, or possess with
14 intent to manufacture, distribute, or dispense, a syn-
15 thetic opioid or product containing a synthetic
16 opioid, unless the opioid or product bears a label
17 clearly identifying a synthetic opioid or product con-
18 taining a synthetic opioid by the nomenclature used
19 by the International Union of Pure and Applied
20 Chemistry (IUPAC).

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

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

3 “(B) A product is described in this subpara-
4 graph if the product—

5 “(i) is the subject of an approved applica-
6 tion as described in section 505(b) or (j) of the
7 Federal Food, Drug, and Cosmetic Act; or

8 “(ii) is exempt from the provisions of sec-
9 tion 505 of such Act relating to new drugs be-
10 cause—

11 “(I) it is intended solely for investiga-
12 tional use as described in section 505(i) of
13 such Act; and

14 “(II) such product is being used ex-
15 clusively for purposes of a clinical trial
16 that is the subject of an effective investiga-
17 tional new drug application.”.

18 (b) CLARIFICATION TO IMPORT AND EXPORT STAT-
19 UTE.—Section 1010 of the Controlled Substances Import
20 and Export Act (21 U.S.C. 960) is amended, in subsection
21 (a)(1), by inserting “305,” before “1002”.

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

24 (1) in subsection (a)—

1 (A) in paragraph (15), by striking “or” at
2 the end;

3 (B) in paragraph (16), by striking the pe-
4 riod at the end and inserting “; or”; and

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

7 “(17) to violate subsection (f) of section 825 of
8 this title.”; and

9 (2) in subsection (c)(1)—

10 (A) by inserting, in subparagraph (A),
11 after “subparagraph (B), (C),” striking “or
12 (D)” and inserting the following: “, (D), (E), or
13 (F)”; and

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

16 “(E) In the case of a violation of paragraph (17) of
17 subsection (a) of this section by an importer, exporter,
18 manufacturer, or distributor (other than as provided in
19 subparagraph (F)), up to \$500,000 per violation. For pur-
20 poses of this subparagraph, a violation is defined as each
21 instance of importation, exportation, manufacturing, dis-
22 tribution, or possession with intent to manufacture or dis-
23 tribute, in violation of paragraph (17) of subsection (a).

24 “(F) In the case of a distribution, dispensing, or pos-
25 session with intent to distribute or dispense in violation

1 of paragraph (17) of subsection (a) of this section at the
2 retail level, up to \$1,000 per violation. Each package, con-
3 tainer or other separate unit containing a synthetic opioid
4 that is distributed, dispensed, or possessed with intent to
5 distribute or dispense at the retail level in violation of such
6 paragraph (17) of subsection (a) shall be considered a sep-
7 arate violation.”.

○