

AMENDMENT IN THE NATURE OF A SUBSTITUTE
TO H.R. 8005
OFFERED BY M. _____

Strike all after the enacting clause and insert the following:

1 **SECTION 1. SHORT TITLE.**

2 This Act may be cited as the “Stop Pills That Kill
3 Act”.

4 SEC. 2. REGULATION OF CERTAIN MACHINES.

(a) DEFINITIONS.—Section 102 of the Controlled Substances Act (21 U.S.C. 802) is amended—

(1) by striking paragraph (38) and inserting the following:

9 “(38) The term ‘regulated person’ means a person
10 who—

11 “(A) manufactures, distributes, imports, or ex-
12 ports a listed chemical;

“(B) manufactures, distributes, delivers, sells,
imports, or exports a tableting machine, encap-
sulating machine, or critical part of a tableting or
encapsulating machine; or

17 “(C) acts as a broker or trader for a regulated
18 transaction involving a listed chemical, tableting ma-

1 chine, encapsulating machine, or critical part of a
2 tableting or encapsulating machine.”;

3 (2) by striking paragraph (39)(B) and inserting
4 the following:

5 “(B) a distribution, delivery, sale, importation,
6 exportation, or international transaction of a
7 tableting machine, encapsulating machine, or critical
8 part of a tableting or encapsulating machine.”;

9 (3) in paragraph (42), by inserting “, tableting
10 machine, encapsulating machine, or critical part of
11 a tableting or encapsulating machine” after “listed
12 chemical”;

13 (4) in paragraph (43), in the matter preceding
14 subparagraph (A)—

15 (A) by striking “an international” and in-
16 serting “a regulated”; and

17 (B) by inserting “, tableting machine, en-
18 capsulating machine, or critical part of a
19 tableting or encapsulating machine” after “list-
20 ed chemical”; and

21 (5) by adding at the end the following:

22 “(61) The term ‘critical part’, when used in reference
23 to a tableting or encapsulating machine, means any of the
24 following integral parts of a tableting or encapsulating
25 machine:

1 “(A) An upper punch.

2 “(B) A lower punch.

3 “(C) A die.

4 “(D) Any additional parts that the Attorney
5 General has determined to be integral to the oper-
6 ation of a tableting or encapsulating machine, pro-
7 vided that such determination—

8 “(i) is made through rulemaking; and

9 “(ii) does not go into effect until the rule-
10 making process has been completed.

11 “(62) The term ‘die’ means a tool that serves as the
12 mold in which a product is compressed to form the desired
13 size and shape of a tablet or capsule.

14 “(63) The term ‘lower punch’ means the punch in-
15 serted into the turret below the die.

16 “(64) The term ‘punch’ means a rod-shaped tool used
17 in producing tablets and other products.

18 “(65) The term ‘upper punch’ means the punch in-
19 serted into the turret above the die.”.

20 (b) REGULATION.—

21 (1) RECORDS OF REGULATED TRANSACTIONS.—

22 Section 310(a) of the Controlled Substances Act (21
23 U.S.C. 830(a)) is amended—

24 (A) in paragraph (1), by striking “or an
25 encapsulating machine” and inserting “, encap-

1 sulating machine, or critical part of a tableting
2 or encapsulating machine”; and

3 (B) in paragraph (2)—

4 (i) by striking “or encapsulating ma-
5 chine” and inserting “, encapsulating ma-
6 chine, or critical part of a tableting or en-
7 capsulating machine”; and

8 (ii) by inserting before the period at
9 the end the following: “and shall identify
10 the tableting machine, encapsulating ma-
11 chine, or critical part of a tableting or en-
12 capsulating machine by means of a serial
13 number that is engraved, cast, or otherwise
14 permanently affixed to a nonremovable
15 part of the tableting machine, encap-
16 sulating machine, or critical part of a
17 tableting or encapsulating machine”.

18 (2) REPORTS TO ATTORNEY GENERAL.—Section
19 310(b)(1) of the Controlled Substances Act (21
20 U.S.C. 830(b)(1)) is amended by striking subpara-
21 graph (D) and inserting the following:

22 “(D) any regulated transaction in a tableting
23 machine, encapsulating machine, or critical part of
24 a tableting or encapsulating machine, including the
25 serial number affixed to the tableting machine, en-

1 capsulating machine, or critical part of a tableting
2 or encapsulating machine.”.

3 (3) REGULATIONS.—

4 (A) IN GENERAL.—Not later than 180
5 days after the date of enactment of this Act,
6 the Attorney General shall promulgate regula-
7 tions carrying out the amendments made by
8 paragraphs (1) and (2).

9 (B) INCLUSION.—The regulations required
10 under subparagraph (A) shall include require-
11 ments regarding serial numbers affixed to
12 tableting machines, encapsulating machines, or
13 critical parts of tableting or encapsulating ma-
14 chines manufactured on or before the date of
15 enactment of this Act.

16 (4) APPLICABILITY.—

17 (A) IN GENERAL.—Except as specified in
18 subparagraph (B), the amendments made by
19 paragraphs (1) and (2) shall apply only to any
20 tableting machine, encapsulating machine, or
21 critical part of a tableting or encapsulating ma-
22 chine manufactured, distributed, delivered, sold,
23 imported, exported, or included in an inter-
24 national transaction after the effective date of

1 the regulations promulgated under paragraph
2 (3).

3 (B) EXCEPTION.—Beginning on the date
4 that is 180 days after the date of the enact-
5 ment of this Act, the amendments made by
6 paragraphs (1) and (2) of this subsection to
7 paragraphs (1) and (2) of section 310(a) of the
8 Controlled Substances Act (21 U.S.C. 830(a))
9 shall apply with respect to a tableting machine,
10 encapsulating machine, or critical part of a
11 tableting or encapsulating machine manufac-
12 tured on or before the date of enactment of this
13 Act.

14 (c) PROHIBITED ACTS.—Section 403(a) of the Con-
15 trolled Substances Act (21 U.S.C. 843(a)) is amended—

16 (1) in paragraph (8), by striking “or” at the
17 end;

18 (2) in paragraph (9), by striking the period at
19 the end and inserting a semicolon; and

20 (3) by adding at the end the following:

21 “(10) to remove, alter, or obliterate any serial
22 number affixed to a tableting machine, encap-
23 sulating machine, or critical part of a tableting or
24 encapsulating machine, that is required to have a se-

1 rial number and with reasonable cause to believe the
2 serial number is so required; or

3 “(11) to transport, ship, receive, possess, dis-
4 tribute, deliver, sell, import, or export a tableting
5 machine, encapsulating machine, or critical part of
6 a tableting or encapsulating machine that is required
7 to have a serial number, knowing that the serial
8 number has been removed, altered, or obliterated,
9 and with reasonable cause to believe the serial num-
10 ber is so required.”.

11 **SEC. 3. PROVIDING FOR EXTRATERRITORIAL JURISDIC-**
12 **TION.**

13 (a) POSSESSION, MANUFACTURE, OR DISTRIBUTION
14 FOR PURPOSES OF UNLAWFUL IMPORTATION.—Section
15 1009 of the Controlled Substances Act (21 U.S.C. 959)
16 is amended—

17 (1) by redesignating subsections (c) and (d) as
18 subsections (d) and (e), respectively;

19 (2) by inserting after subsection (b) the fol-
20 lowing:

21 “(c) It shall be unlawful for any person to manufac-
22 ture or distribute a tableting machine, encapsulating ma-
23 chine, or critical part of a tableting or encapsulating ma-
24 chine—

1 “(1) intending or knowing that the tableting
2 machine, encapsulating machine, or critical part of
3 a tableting or encapsulating machine will be used to
4 illicitly manufacture a controlled substance or listed
5 chemical; and

6 “(2) intending, knowing, or having reasonable
7 cause to believe that the tableting machine, encap-
8 sulating machine, or critical part of a tableting or
9 encapsulating machine will be unlawfully imported
10 into the United States.”; and

11 (3) in subsection (d), as so redesignated—

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

14 (B) in paragraph (2), by striking the pe-
15 riod at the end and inserting “; or”; and

16 (C) by adding at the end the following:

17 “(3) manufacture or distribute a tableting ma-
18 chine, encapsulating machine, or critical part of a
19 tableting or encapsulating machine—

20 “(A) intending or knowing that the
21 tableting machine, encapsulating machine, or
22 critical part of a tableting or encapsulating ma-
23 chine will be used to illicitly manufacture a con-
24 trolled substance or listed chemical; and

1 “(B) intending, knowing, or having reason-
2 able cause to believe that the tableting machine,
3 encapsulating machine, or critical part of a
4 tableting or encapsulating machine will be un-
5 lawfully imported into the United States.”.

6 (b) PROHIBITED ACTS.—Section 1010 of the Con-
7 trolled Substances Act (21 U.S.C. 960) is amended—

8 (1) in subsection (d)—

9 (A) in paragraph (6), by striking “or” at
10 the end;

11 (B) in paragraph (7)—

12 (i) by striking “section 959 of this
13 title” and inserting “section 1009”; and

14 (ii) by striking the period at the end
15 and inserting “; or”;

16 (C) by inserting after paragraph (7) the
17 following:

18 “(8) manufactures or distributes a tableting
19 machine, encapsulating machine, or critical part of
20 a tableting or encapsulating machine in violation of
21 section 1009,”; and

22 (D) in the matter following paragraph (8),
23 as so inserted, by striking “shall be fined” and
24 all that follows through “or both” and inserting
25 the following: “shall be fined in accordance with

1 title 18, United States Code, imprisoned for the
2 applicable period described in subsection (e), or
3 both”; and

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

5 “(e) The applicable period described in this sub-
6 section is the following:

7 “(1) In the case of a violation of paragraph (1)
8 or (3) of subsection (d) involving a list I chemical,
9 not more than 20 years.

10 “(2) Subject to paragraph (4), in the case of a
11 violation of paragraph (7) of subsection (d), not
12 more than 10 years.

13 “(3) Subject to paragraph (4), in the case of a
14 violation of paragraph (8) of subsection (d), not
15 more than 8 years.

16 “(4) In the case of a violation of paragraph (7)
17 or (8) of subsection (d) that involves more than
18 1,000 kilograms of a chemical or product or more
19 than 100 machines that are tableting machines or
20 encapsulating machines, not more than 15 years.

21 “(5) In the case of any other violation of sub-
22 section (d), not more than 10 years.”.

23 (c) UNITED STATES SENTENCING COMMISSION.—
24 Pursuant to its authority under section 994(p) of title 28,
25 United States Code, the United States Sentencing Com-

1 mission shall review and amend the Federal sentencing
2 guidelines and policy statements of the Commission in ac-
3 cordance with this Act and the amendments made by this
4 Act.

5 **SEC. 4. COUNTERFEIT PILLS CONTAINING AN ILLICIT SYN-**
6 **THETIC SUBSTANCE.**

7 (a) DEFINITION.—In this Act, the term “counterfeit
8 pill containing an illicit synthetic substance” means a sub-
9 stance in pill or tablet form that—

10 (1) is a counterfeit substance, as defined in sec-
11 tion 102(7) of the Controlled Substances Act (21
12 U.S.C. 802(7)); and

13 (2) contains fentanyl, an analogue of fentanyl,
14 a fentanyl-related substance, methamphetamine, an
15 illicit depressant or stimulant substance, an illicit
16 narcotic, or an illicit synthetic opioid.

17 (b) PROHIBITED ACTS.—Section 403(d)(2) of the
18 Controlled Substances Act (21 U.S.C. 843(d)(2)) is
19 amended, in the matter preceding subparagraph (A), by
20 inserting “, fentanyl, an analogue of fentanyl, or a
21 fentanyl-related substance” after “methamphetamine”.

22 (c) COMPREHENSIVE PLAN.—

23 (1) IN GENERAL.—Not later than 180 days
24 after the date of enactment of this Act, the Adminis-
25 trator of the Drug Enforcement Administration shall

1 establish and implement an operation and response
2 plan to address counterfeit pills containing an illicit
3 synthetic substance.

4 (2) CONTENTS.—The plan required under para-
5 graph (1) shall include—

6 (A) strategies to enable and empower Fed-
7 eral law enforcement efforts to investigate and
8 seize counterfeit pills containing an illicit syn-
9 thetic substance;

10 (B) specific ways that education and pre-
11 vention efforts to stop the use of counterfeit
12 pills containing an illicit synthetic substance
13 will be increased, including—

14 (i) how ongoing efforts, such as Oper-
15 ation Engage, are effective in increasing
16 education and prevention; and

17 (ii) how such ongoing efforts are tai-
18 lored to youth and teen access; and

19 (C) an audit of current campaigns on
20 counterfeit pills containing an illicit synthetic
21 substance, including a review of data and other
22 available information on how the campaigns can
23 be tailored, adjusted, or improved to better ad-
24 dress the flow of such counterfeit pills.

25 (3) REPORT TO CONGRESS.—

1 (A) REPORT.—Not later than 1 year after
2 the date of enactment of this Act, and every
3 year thereafter through fiscal year 2031, the
4 Attorney General, in consultation with the Ad-
5 ministrator of the Drug Enforcement Adminis-
6 tration and the Director of the Office of Na-
7 tional Drug Control Policy, shall submit to Con-
8 gress a report containing information regarding
9 the collection of counterfeit pills containing an
10 illicit synthetic substance and prosecutions un-
11 dertaken in connection with such counterfeit
12 pills.

13 (B) CONTENTS.—The report required
14 under paragraph (1) shall include the following:

15 (i) Data on the aggregate number of
16 counterfeit pills containing an illicit syn-
17 thetic substance that have been seized and
18 collected by Federal law enforcement agen-
19 cies.

20 (ii) A description of pharmaceutical
21 markings used for counterfeit pills con-
22 taining an illicit synthetic substance, in-
23 cluding how the markings compare to re-
24 quired labeling for products approved by
25 the Food and Drug Administration.

1 (iii) A breakdown of which illicit sub-
2 stances are present in counterfeit pills con-
3 taining an illicit synthetic substance.

4 (iv) Data outlining the geographic ori-
5 gin and points of seizure of counterfeit
6 pills containing an illicit synthetic sub-
7 stance.

8 (v) Data on the charges filed pursu-
9 ant to paragraph (1) or (2) of section
10 401(a) of the Controlled Substances Act
11 (21 U.S.C. 841(a)) in relation to counter-
12 feit pills containing an illicit synthetic sub-
13 stance, unless disclosure of the data
14 would—

15 (I) require unsealing an indict-
16 ment; or

17 (II) undermine investigations and
18 charges brought by the Department of
19 Justice.

20 (vi) Data on the convictions and sen-
21 tences against those who are found guilty
22 under paragraph (1) or (2) of section
23 401(a) of the Controlled Substances Act
24 (21 U.S.C. 841(a)) as it pertains to coun-

1 terfeit pills containing an illicit synthetic
2 substance.

3 (vii) Any prevention measures that
4 the Department of Justice, the Drug En-
5 forcement Administration, or the Office of
6 National Drug Control Policy are under-
7 taking to limit and reduce the spread of
8 counterfeit pills containing an illicit syn-
9 thetic substance, including ongoing public
10 awareness campaigns.

Amend the title so as to read: “A bill to amend the Controlled Substances Act to prevent the misuse of a tableting machine, encapsulating machine, or critical part of a tableting and encapsulating machine for the illicit manufacture of a controlled substance or listed chemical, and for other purposes.”.

