

112TH CONGRESS
2D SESSION

H. R. 6160

To amend the Federal Food, Drug, and Cosmetic Act to incentivize the development of tamper-resistant drugs.

IN THE HOUSE OF REPRESENTATIVES

JULY 19, 2012

Mr. KEATING (for himself, Mrs. BONO MACK, Mr. ROGERS of Kentucky, Mr. LYNCH, Mr. RAHALL, Mr. TOWNS, and Mr. TIERNEY) introduced the following bill; which was referred to the Committee on Energy and Commerce

A BILL

To amend the Federal Food, Drug, and Cosmetic Act to incentivize the development of tamper-resistant drugs.

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.**

4 This Act may be cited as the “Stop Tampering of
5 Prescription Pills Act of 2012”.

6 **SEC. 2. TAMPER-RESISTANT TECHNOLOGY.**

7 (a) DEFINITION.—Section 201 of the Federal Food,
8 Drug, and Cosmetic Act (21 U.S.C. 321) is amended by
9 adding at the end the following:

1 “(ss) The term ‘tamper-resistant drug’ means a drug
2 that—

3 “(1) contains as an active moiety a controlled
4 substance that has been classified as opium, an opi-
5 ate, or a derivative thereof, as such terms are de-
6 fined or used in section 102 of the Controlled Sub-
7 stances Act;

8 “(2) has been formulated for oral administra-
9 tion; and

10 “(3)(A) exhibits physicochemical properties
11 (demonstrated by in vitro, in vivo, or other testing,
12 or some combination thereof, as determined appro-
13 priate by the Secretary) that make product manipu-
14 lation significantly more difficult or ineffective in al-
15 tering the characteristics of the drug for purposes of
16 misuse or abuse when compared to drugs without
17 such properties; or

18 “(B) contains one or more additional active or
19 inactive ingredients that are intended to deter abuse
20 through potential pharmacological effects, the effec-
21 tiveness of which has been demonstrated by at least
22 one adequate and well-controlled investigation.”.

23 (b) REQUIRED INFORMATION IN APPLICATION FOR
24 APPROVAL OF BRAND NAME DRUGS.—Section 505(b) of

1 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
2 355(b)) is amended by adding at the end the following:

3 “(7) TAMPER-RESISTANT DRUGS.—If an appli-
4 cation submitted under this subsection is potentially
5 subject to refusal under subsection (d)(7), the appli-
6 cation shall include such information as the Sec-
7 retary determines necessary to demonstrate that the
8 application is not subject to such refusal.”.

9 (c) APPROVAL OF NEW BRAND NAME DRUGS.—Sec-
10 tion 505(d) of the Federal Food, Drug, and Cosmetic Act
11 (21 U.S.C. 355(d)) is amended—

12 (1) by inserting “(7)(A) such drug has been
13 formulated for oral administration; (B) such drug
14 contains as an active moiety a controlled substance
15 that has been classified as opium, an opiate, or a de-
16 rivative thereof, as such terms are defined or used
17 in section 102 of the Controlled Substances Act; (C)
18 such drug is not a tamper-resistant drug; and (D)
19 the Secretary has previously approved pursuant to
20 an application submitted under subsection (b) or (j)
21 a drug that (i) contains the same active moiety; (ii)
22 is a tamper-resistant drug, and (iii) has not been
23 discontinued from marketing; or” after “(6) the ap-
24 plication failed to contain the patent information
25 prescribed by subsection (b); or”;

1 (2) by striking “(7) based on fair” and insert-
2 ing “(8) based on fair”;

3 (3) by striking “clauses (1) through (6)” and
4 inserting “paragraphs (1) through (7)”; and

5 (4) by inserting “The Secretary may issue an
6 order approving an application, even if paragraph
7 (7) applies, upon a finding that paragraphs (1)
8 through (6) and paragraph (8) do not apply and
9 that such approval is necessary either to prevent or
10 alleviate a drug shortage or to otherwise address a
11 significant unmet public health need.” before “As
12 used in this subsection and subsection (e)”.

13 (d) **GENERIC DRUGS.**—Section 505(j) of the Federal
14 Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)) is
15 amended—

16 (1) in paragraph (2)—

17 (A) subparagraph (A)—

18 (i) in clause (vii), by striking “and” at
19 the end;

20 (ii) in clause (viii), by striking the pe-
21 riod at the end and inserting “; and”;

22 (iii) by inserting after clause (viii) the
23 following:

24 “(ix) if the listed drug is a tamper-resistant
25 drug due to its physicochemical properties, informa-

1 tion from comparative in vitro, in vivo, or other test-
2 ing, or some combination thereof, as appropriate
3 based on the type of data submitted for the listed
4 drug, that demonstrates the new drug resists manip-
5 ulation or the effect of manipulation to a degree at
6 least comparable to the listed drug.”; and

7 (iv) in the continuation text at the
8 end of the subparagraph, by striking
9 “clauses (i) through (viii)” and inserting
10 “clauses (i) through (ix)”;

11 (B) in subparagraph (C)—

12 (i) in clause (i), by striking “or” at
13 the end;

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

16 (iii) by adding at the end the fol-
17 lowing:

18 “(iii) that the listed drug is a tamper-resistant
19 drug and one or more of the new drug’s active
20 moieties differ in any material respect (in amount or
21 otherwise) from those of the listed drug.”;

22 (2) in paragraph (5), by adding at the end the
23 following:

24 “(G) If a drug has been approved pursuant to an ap-
25 plication submitted under paragraph (2), and thereafter

1 the listed drug referred to in the application becomes a
2 tamper-resistant drug, the drug so approved shall not be
3 considered to be bioequivalent to, or to have the same
4 therapeutic effect as, the listed drug (as described in para-
5 graph (2)(A)(iv)) unless and until the drug so approved
6 has been found by the Secretary to meet the requirements
7 of paragraph (2)(A)(ix).”; and

8 (3) in paragraph (6)—

9 (A) by striking “(6) If a drug” and insert-
10 ing “(6)(A) If a drug”;

11 (B) by striking “(A) for the” and inserting
12 “(i) for the”;

13 (C) by striking “(B) if the” and inserting
14 “(ii) if the”; and

15 (D) by adding at the end the following:

16 “(B) For purposes of this paragraph and paragraph
17 (7)(C), a withdrawal or suspension of a drug formulated
18 for oral administration shall be considered to have been
19 for safety or effectiveness reasons if—

20 “(i) the approval of a listed drug, which is not
21 a tamper-resistant drug, is withdrawn or suspended,
22 or a listed drug, which is not a tamper-resistant
23 drug, is withdrawn from sale; and

1 “(ii) the Secretary has previously approved pur-
2 suant to an application under subsection (b) a drug
3 that—

4 “(I) is in the same dosage form;

5 “(II) contains the same controlled sub-
6 stance as an active moiety;

7 “(III) is a tamper-resistant drug; and

8 “(IV) has not been discontinued from mar-
9 keting.”.

10 (e) WITHDRAWAL OF PREVIOUSLY APPROVED
11 BRAND NAME AND GENERIC DRUGS.—Section 505(e) of
12 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
13 355(e)) is amended—

14 (1) by inserting “or (6)(A) the drug contains as
15 an active moiety a controlled substance that has
16 been classified as opium, an opiate, or a derivative
17 thereof, as such terms are defined or used in section
18 102 of the Controlled Substances Act; (B) the drug
19 is formulated for oral administration; (C) the drug
20 is not a tamper-resistant drug; and (D) the Sec-
21 retary has previously approved pursuant to an appli-
22 cation submitted under subsection (b) or (j) a drug
23 that contains the same active moiety, is a tamper-
24 resistant drug, and has not been discontinued from
25 marketing” before “: *Provided*,”; and

1 (2) by adding at the end the following: “The
2 Secretary may waive the application of paragraph
3 (6) of the first sentence of this subsection in the
4 case of a drug intended for use in a special needs
5 population. In withdrawing (under paragraph (6) of
6 the first sentence of this subsection) the approval of
7 an application with respect to any drug, the Sec-
8 retary shall, on a case-by-case basis, delay the effec-
9 tive date of such withdrawal for a period deemed
10 sufficient by the Secretary to give the sponsor an op-
11 portunity to obtain approval under this section for
12 a formulation of the drug meeting the criteria de-
13 scribed in paragraph (2) of the definition of a ‘tam-
14 per-resistant drug’ in section 201(ss).”.

15 (f) LISTED DRUGS.—Section 505(j)(7) of the Federal
16 Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)) is
17 amended by adding at the end the following:

18 “(D) Beginning 60 days after the date of the enact-
19 ment of the Stop Tampering of Prescription Pills Act of
20 2012, the Secretary shall—

21 “(i) include in the list under subparagraph (A)
22 a list of each drug or category of drugs which the
23 Secretary has found to be tamper-resistant drugs;
24 and

25 “(ii) update the list under subparagraph (A)—

1 “(I) to remove from the list of tamper-re-
2 sistant drugs any drug the Secretary later de-
3 termines is not a tamper-resistant drug; and

4 “(II) as required by subparagraph (C) to
5 reflect the application of paragraph (6)(B) to
6 drugs that are withdrawn or suspended.”.

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