

114TH CONGRESS
1ST SESSION

H. R. 2335

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

IN THE HOUSE OF REPRESENTATIVES

MAY 14, 2015

Mr. KEATING (for himself, Mr. ROGERS of Kentucky, Mr. ROONEY of Florida, Mr. LYNCH, Mr. ADERHOLT, Mr. BUCHANAN, Mr. KENNEDY, Mr. MCGOVERN, and Ms. SCHAKOWSKY) 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 abuse-deterrent 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 2015”.

6 **SEC. 2. ABUSE-DETERRENT 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 ‘abuse-deterrent 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) ABUSE-DETERRENT 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 an abuse-deterrent 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 an abuse-deterrent 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 an abuse-deter-
25 rent drug due to its physicochemical properties,

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

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

12 (B) in subparagraph (C)—

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

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

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

19 “(iii) that the listed drug is an abuse-de-
20 terrent drug and one or more of the new drug’s
21 active moieties differ in any material respect (in
22 amount or otherwise) from those of the listed
23 drug.”;

24 (2) in paragraph (5), by adding at the end the
25 following:

1 “(G) If a drug has been approved pursuant to
2 an application submitted under paragraph (2), and
3 thereafter the listed drug referred to in the applica-
4 tion becomes an abuse-deterrent drug, the drug so
5 approved shall not be considered to be bioequivalent
6 to, or to have the same therapeutic effect as, the
7 listed drug (as described in paragraph (2)(A)(iv))
8 unless and until the drug so approved has been
9 found by the Secretary to meet the requirements of
10 paragraph (2)(A)(ix).”; and

11 (3) in paragraph (6)—

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

14 (B) by striking “(A) for the” and inserting
15 “(i) for the”;

16 (C) by striking “(B) if the” and inserting
17 “(ii) if the”; and

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

19 “(B) For purposes of this paragraph and para-
20 graph (7)(C), a withdrawal or suspension of a drug
21 formulated for oral administration shall be consid-
22 ered to have been for safety or effectiveness reasons
23 if—

24 “(i) the approval of a listed drug, which is
25 not an abuse-deterrent drug, is withdrawn or

1 suspended, or a listed drug, which is not an
2 abuse-deterrent drug, is withdrawn from sale;
3 and

4 “(ii) the Secretary has previously approved
5 pursuant to an application under subsection (b)
6 a drug that—

7 “(I) is in the same dosage form;

8 “(II) contains the same controlled
9 substance as an active moiety;

10 “(III) is an abuse-deterrent drug; and

11 “(IV) has not been discontinued from
12 marketing.”.

13 (e) WITHDRAWAL OF PREVIOUSLY APPROVED
14 BRAND NAME AND GENERIC DRUGS.—Section 505(e) of
15 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
16 355(e)) is amended—

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

1 that contains the same active moiety, is an abuse-de-
2 terrent drug, and has not been discontinued from
3 marketing” before “: *Provided*,”; and

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

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

21 “(D) Beginning 60 days after the date of the
22 enactment of the Stop Tampering of Prescription
23 Pills Act of 2015, the Secretary shall—

24 “(i) include in the list under subparagraph

25 (A) a list of each drug or category of drugs

1 which the Secretary has found to be abuse-de-
2 terrent drugs; and

3 “(ii) update the list under subparagraph
4 (A)—

5 “(I) to remove from the list of abuse-
6 deterrent drugs any drug the Secretary
7 later determines is not an abuse-deterrent
8 drug; and

9 “(II) as required by subparagraph (C)
10 to reflect the application of paragraph
11 (6)(B) to drugs that are withdrawn or sus-
12 pended.”.

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