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(Original Signature of Member)

118TH CONGRESS
1ST SESSION

H. R. _____

To amend the Federal Food, Drug, and Cosmetic Act to prevent the use of patents, trade secrets, or other intellectual property to inhibit competition.

IN THE HOUSE OF REPRESENTATIVES

Ms. SLOTKIN introduced the following bill; which was referred to the Committee on _____

A BILL

To amend the Federal Food, Drug, and Cosmetic Act to prevent the use of patents, trade secrets, or other intellectual property to inhibit competition.

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 “Increasing Prescription
5 Drug Competition Act”.

1 **SEC. 2. PREVENTING THE USE OF PATENTS, TRADE SE-**
2 **CRETS, OR OTHER INTELLECTUAL PROPERTY**
3 **ON RISK EVALUATION AND MITIGATION**
4 **STRATEGIES TO INHIBIT COMPETITION.**

5 Section 505–1 of the Federal Food, Drug, and Cos-
6 metic Act (21 U.S.C. 355–1) is amended by adding at the
7 end the following:

8 “(n) **ADDITIONAL REQUIREMENTS.**—

9 “(1) **PATENTS CLAIMING REMS.**—If an applica-
10 tion under subsection (b)(2) or (j) of section 505 in-
11 cludes a certification under subsection (b)(2)(A) or
12 (j)(2)(A)(vii) of section 505 with respect to a patent
13 that claims an aspect of the elements to assure safe
14 use of a risk evaluation and mitigation strategy re-
15 quirements under subsection (f) for the applicable
16 listed drug, such certification shall have no effect on
17 the effective date of the approval of the application,
18 notwithstanding subparagraphs (B) and (C) of sec-
19 tion 505(c)(3) and clauses (ii) and (iii) of section
20 505(j)(5)(B).

21 “(2) **DAMAGES.**—In the event that the sponsor
22 of another application under section 505 of this Act
23 or section 351 of the Public Health Service Act in-
24 fringes a patent, trade secret, or any other intellec-
25 tual property held by the sponsor or holder to com-
26 ply with risk evaluation and mitigation strategy re-

1 requirements under this section, the sponsor or holder
2 of the approved application shall not seek, or claim
3 entitlement to, any remedy other than damages arising
4 from the infringement.

5 “(3) CLARIFICATIONS.—Nothing in this section
6 shall be construed as —

7 “(A) prohibiting the sponsor or holder of
8 an approved application from allowing the sponsor
9 of another application under section 505 of
10 this Act or section 351 of the Public Health
11 Service Act to use the patent, trade secret, or
12 any other intellectual property other than as described
13 in this subsection;

14 “(B) preventing a sponsor of an application
15 under section 505 of this Act or section
16 351 of the Public Health Service Act from
17 using a different, comparable aspect of the elements
18 to assure safe use as authorized under
19 this section;

20 “(C) in any way negating the applicability
21 of a risk evaluation and mitigation strategy
22 with elements to assure safe use, as otherwise
23 required under this section; or

24 “(D) limiting the application of any provision
25 of the antitrust laws (as defined in sub-

1 section (a) of the first section of the Clayton
2 Act (15 U.S.C. 12(a)).”.