

115TH CONGRESS
1ST SESSION

S. 1049

To allow the Secretary of Health and Human Services to require that risk evaluation and mitigation strategies for certain drugs include communication plans that provide information about drug formulations or properties described in the drug labeling.

IN THE SENATE OF THE UNITED STATES

MAY 4, 2017

Ms. HASSAN (for herself and Mr. YOUNG) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

A BILL

To allow the Secretary of Health and Human Services to require that risk evaluation and mitigation strategies for certain drugs include communication plans that provide information about drug formulations or properties described in the drug labeling.

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 “Opioid Addiction Risk
5 Transparency Act”.

1 **SEC. 2. REMS COMMUNICATION PLANS.**

2 Section 505–1(e)(3) of the Federal Food, Drug, and
3 Cosmetic Act (21 U.S.C. 355–1(e)(3)) is amended—

4 (1) in subparagraph (B), by striking “; or”;

5 (2) in subparagraph (C), by striking the period
6 and inserting “; or”; and

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

8 “(D) disseminating information to health
9 care providers about the meaning of terms re-
10 lated to drug formulations or properties that
11 are described in the drug labeling, including in-
12 formation about the limitations or patient care
13 implications of such formulations or properties,
14 and how such formulations or properties may
15 be related to serious adverse drug events associ-
16 ated with use of the drug.”.

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