

115TH CONGRESS
2D SESSION

H. R. 5803

To amend the Federal Food, Drug, and Cosmetic Act to authorize the Secretary of Health and Human Services to consider the potential for misuse and abuse when determining whether to approve certain drugs, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

MAY 15, 2018

Mr. GENE GREEN of Texas 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 authorize the Secretary of Health and Human Services to consider the potential for misuse and abuse when determining whether to approve certain drugs, and for other purposes.

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 “Saving American Fam-
5 ilies through Efficacy and Trusted Ways Act of 2018” or
6 the “SAFETY Act of 2018”.

1 **SEC. 2. CONSIDERATION OF POTENTIAL FOR MISUSE AND**
2 **ABUSE REQUIRED FOR DRUG APPROVAL.**

3 (a) IN GENERAL.—Section 505(d) of the Federal
4 Food, Drug, and Cosmetic Act (21 U.S.C. 355(d)) is
5 amended—

6 (1) in the first sentence—

7 (A) by striking “or (7)” and inserting
8 “(7)”; and

9 (B) by inserting “; or (8) if the drug is or
10 contains a controlled substance for which a list-
11 ing in any schedule is in effect under the Con-
12 trolled Substances Act or that is permanently
13 scheduled pursuant to section 201 of such Act,
14 on the basis of information submitted to him as
15 part of the application, or upon the basis of any
16 other information before him with respect to
17 such drug, the drug is unsafe for use due to the
18 risks of abuse or misuse or there is insufficient
19 information to show that the drug is safe for
20 use considering such risks;” before “he shall
21 issue an order refusing to approve the applica-
22 tion”; and

23 (2) in the second sentence, by striking “(6)”
24 and inserting “(8)”.

1 (b) WITHDRAWAL AUTHORITY.—Section 505(e) of
2 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
3 355(e)) is amended in the first sentence—

4 (1) by striking “or (5)” and inserting “(5)”;
5 and

6 (2) by inserting the following: “; or (6) that, in
7 the case of a drug that is or contains a controlled
8 substance for which a listing in any schedule is in
9 effect under the Controlled Substances Act or that
10 is permanently scheduled pursuant to section 201 of
11 such Act, on the basis of new information before him
12 with respect to such drug, evaluated together with
13 the information available to him when the applica-
14 tion was approved, that the drug is unsafe for use
15 due to the risks of abuse or misuse” after “of a ma-
16 terial fact”.

17 (c) RULE OF CONSTRUCTION.—Nothing in the
18 amendments made by this section shall be construed to
19 limit or narrow, in any manner, the meaning or applica-
20 tion of the provisions of paragraphs (1), (2), (3), (4), (5),
21 and (7) of section 505(d) of the Federal Food, Drug, and
22 Cosmetic Act (21 U.S.C. 355(d)) or paragraphs (1) and
23 (2) of section 505(e) of such Act (21 U.S.C. 355(e)).

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