

117TH CONGRESS  
2D SESSION

# H. R. 6545

To amend the Federal Food, Drug, and Cosmetic Act to expand certain authorities with respect to the recall of controlled substances to apply with respect to all drugs, and for other purposes.

---

## IN THE HOUSE OF REPRESENTATIVES

FEBRUARY 1, 2022

Mr. KIM of New Jersey 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 expand certain authorities with respect to the recall of controlled substances to apply with respect to all 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 “Protecting Americans  
5 from Unsafe Drugs Act of 2022”.

1 **SEC. 2. NOTIFICATION, NONDISTRIBUTION, AND RECALL**  
2 **OF DRUGS.**

3 (a) ORDER TO CEASE DISTRIBUTION AND RE-  
4 CALL.—Section 569D of the Federal Food, Drug, and  
5 Cosmetic Act (21 U.S.C. 360bbb–8d) is amended—

6 (1) in the section heading, by striking “**CON-**  
7 **TROLLED SUBSTANCES**” and inserting “**DRUGS**”;

8 (2) by striking “controlled substance” each  
9 place such term appears and inserting “drug”;

10 (3) in subsection (b)—

11 (A) by striking “controlled substances”  
12 and inserting “drugs”; and

13 (B) by inserting “of subsection (a)” after  
14 “an order pursuant to paragraph (1) or an  
15 amended order pursuant to subparagraph (B)  
16 or (C) of paragraph (3)”;

17 (4) in subsection (c), by striking “or an official  
18 senior to such Director” and inserting “or the Direc-  
19 tor of the Center for Biologics Evaluation and Re-  
20 search (or an official senior to either such Direc-  
21 tor)”.

22 (b) IMPORTS AND EXPORTS.—Section 801(a) of the  
23 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 381(a))  
24 is amended by striking “is a controlled substance subject

- 1 to an order under section 569D” and inserting “is a drug
- 2 subject to an order under section 569D”.

○