

117TH CONGRESS  
2D SESSION

# H. R. 8202

To amend the Federal Food, Drug, and Cosmetic Act to require a recall of electronic nicotine delivery systems that have not been subject to premarket review, and for other purposes.

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## IN THE HOUSE OF REPRESENTATIVES

JUNE 23, 2022

Mr. DESAULNIER introduced the following bill; which was referred to the Committee on Energy and Commerce

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## A BILL

To amend the Federal Food, Drug, and Cosmetic Act to require a recall of electronic nicotine delivery systems that have not been subject to premarket review, 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 “Preventing Vape Use  
5 Act”.

1 **SEC. 2. INCLUSION OF ENDS IN DEFINITION OF TOBACCO**  
2 **PRODUCT.**

3 (a) CONFIRMATION OF INCLUSION OF ENDS IN  
4 DEFINITION OF TOBACCO PRODUCT.—Section 201(rr)(1)  
5 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C.  
6 321(rr)(1)) is amended by adding at the end the following:  
7 “Such term includes an electronic nicotine delivery sys-  
8 tem.”.

9 (b) ENDS DEFINED.—Section 201 of the Federal  
10 Food, Drug, and Cosmetic Act (21 U.S.C. 321) is amend-  
11 ed by adding at the end the following:

12 “(ss) The term ‘electronic nicotine delivery system’  
13 means a tobacco product that is an electronic device that  
14 delivers nicotine, flavor, or another substance via an aero-  
15 solized solution to the user inhaling from the device (in-  
16 cluding e-cigarettes, e-hookah, e-cigars, vape pens, ad-  
17 vanced refillable personal vaporizers, and electronic pipes)  
18 and any component, liquid, part, or accessory of such a  
19 device, whether or not sold separately.”.

20 **SEC. 3. MANDATORY RECALL OF ENDS PENDING PRE-**  
21 **MARKET REVIEW.**

22 Section 908(c) of the Federal Food, Drug, and Cos-  
23 metic Act (21 U.S.C. 387h(c)) is amended by adding at  
24 the end the following:

25 “(4) MANDATORY RECALL OF ENDS PENDING  
26 PREMARKET REVIEW.—

1           “(A) ISSUANCE OF ORDER.—Notwith-  
2           standing paragraphs (1) and (2), in the case of  
3           a tobacco product that is an electronic nicotine  
4           delivery system with respect to which, as of the  
5           date of the enactment of this subparagraph, an  
6           order under section 910(c)(1)(A)(i) has not  
7           been issued, the Secretary shall, not later than  
8           60 days after such date of enactment, issue an  
9           order requiring—

10                   “(i) the appropriate person (including  
11                   a manufacturer, importer, distributor, or  
12                   retailer of the tobacco product) to imme-  
13                   diately cease distribution of such tobacco  
14                   product; and

15                   “(ii) the recall of such tobacco prod-  
16                   uct.

17           “(B) HEARING.—The order under sub-  
18           paragraph (A) shall provide the person subject  
19           to the order with an opportunity for an infor-  
20           mal hearing, to be held not later than 10 days  
21           after the date of the issuance of the order, on  
22           the actions required by the order and the terms  
23           of the recall required by such order.

24           “(C) CONTENTS OF ORDER.—An order  
25           issued under subparagraph (A) shall specify a

1 timetable in which the tobacco product recall  
2 will occur and shall require periodic reports to  
3 the Secretary describing the progress of the re-  
4 call.

5 “(D) NOTICE.—An order under subpara-  
6 graph (A)—

7 “(i) shall not include recall of a to-  
8 bacco product from individuals; and

9 “(ii) shall provide for notice to per-  
10 sons subject to the risks associated with  
11 the use of such tobacco product.

12 “(E) ASSISTANCE ALLOWED.—In providing  
13 the notice required by subparagraph (D)(ii), the  
14 Secretary may use the assistance of retailers  
15 and other persons who distributed such tobacco  
16 product. If a significant number of such per-  
17 sons cannot be identified, the Secretary shall  
18 notify such persons under section 705(b).

19 “(F) WITHDRAWAL OF ORDER.—The Sec-  
20 retary may only withdraw an order issued  
21 under subparagraph (A) with respect to a to-  
22 bacco product described in such subparagraph  
23 upon the issuance of an order section  
24 910(c)(1)(A)(i) with respect to that product.”.

1 **SEC. 4. NO EXEMPTIONS ALLOWED FOR ENDS.**

2 Section 910(a) of the Federal Food, Drug, and Cos-  
3 metic Act (21 U.S.C. 387j(a)) is amended—

4 (1) in paragraph (2), by adding at the end the  
5 following:

6 “(C) APPLICATION TO ENDS.—Notwith-  
7 standing clauses (i) and (ii) of subparagraphs  
8 (A) and (B), beginning on the date that is 60  
9 days after the date of the enactment of this  
10 subparagraph—

11 “(i) electronic nicotine delivery sys-  
12 tems are deemed to be not substantially  
13 equivalent to any predicate tobacco prod-  
14 uct; and

15 “(ii) the requirement for premarket  
16 review under subparagraph (A) shall apply  
17 to a tobacco product that is an electronic  
18 nicotine delivery system.”; and

19 (2) in paragraph (3)(C)—

20 (A) by striking “equivalent to a predicate”  
21 and inserting the following: “equivalent—

22 “(A) to a predicate”;

23 (B) by striking “adulterated.” and insert-  
24 ing “adulterated; or”; and

25 (C) by adding at the end the following:

1                   “(B) beginning on the date that is 60 days  
2                   after the date of the enactment of this subpara-  
3                   graph, if the tobacco product is an electronic  
4                   nicotine delivery system.”.

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