

**AMENDMENT TO RULES COMMITTEE PRINT**

**117-54**

**OFFERED BY MR. DESAULNIER OF CALIFORNIA**

At the end of division E, add the following:

1 **TITLE LIX—PREVENTING VAPE**  
2 **USE**

3 **SEC. 5901. INCLUSION OF ENDS IN DEFINITION OF TO-**  
4 **BACCO PRODUCT.**

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

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

14 “(ss) The term ‘electronic nicotine delivery system’  
15 means a tobacco product that is an electronic device that  
16 delivers nicotine, flavor, or another substance via an aero-  
17 solized solution to the user inhaling from the device (in-  
18 cluding e-cigarettes, e-hookah, e-cigars, vape pens, ad-  
19 vanced refillable personal vaporizers, and electronic pipes)

1 and any component, liquid, part, or accessory of such a  
2 device, whether or not sold separately.”.

3 **SEC. 5902. MANDATORY RECALL OF ENDS PENDING PRE-**  
4 **MARKET REVIEW.**

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

8 “(4) MANDATORY RECALL OF ENDS PENDING  
9 PREMARKET REVIEW.—

10 “(A) ISSUANCE OF ORDER.—Notwith-  
11 standing paragraphs (1) and (2), in the case of  
12 a tobacco product that is an electronic nicotine  
13 delivery system with respect to which, as of the  
14 date of the enactment of this subparagraph, an  
15 order under section 910(c)(1)(A)(i) has not  
16 been issued, the Secretary shall, not later than  
17 60 days after such date of enactment, issue an  
18 order requiring—

19 “(i) the appropriate person (including  
20 a manufacturer, importer, distributor, or  
21 retailer of the tobacco product) to imme-  
22 diately cease distribution of such tobacco  
23 product; and

24 “(ii) the recall of such tobacco prod-  
25 uct.

1           “(B) HEARING.—The order under sub-  
2 paragraph (A) shall provide the person subject  
3 to the order with an opportunity for an infor-  
4 mal hearing, to be held not later than 10 days  
5 after the date of the issuance of the order, on  
6 the actions required by the order and the terms  
7 of the recall required by such order.

8           “(C) CONTENTS OF ORDER.—An order  
9 issued under subparagraph (A) shall specify a  
10 timetable in which the tobacco product recall  
11 will occur and shall require periodic reports to  
12 the Secretary describing the progress of the re-  
13 call.

14           “(D) NOTICE.—An order under subpara-  
15 graph (A)—

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

18           “(ii) shall provide for notice to per-  
19 sons subject to the risks associated with  
20 the use of such tobacco product.

21           “(E) ASSISTANCE ALLOWED.—In providing  
22 the notice required by subparagraph (D)(ii), the  
23 Secretary may use the assistance of retailers  
24 and other persons who distributed such tobacco  
25 product. If a significant number of such per-

1           sons cannot be identified, the Secretary shall  
2           notify such persons under section 705(b).

3           “(F) WITHDRAWAL OF ORDER.—The Sec-  
4           retary may only withdraw an order issued  
5           under subparagraph (A) with respect to a to-  
6           bacco product described in such subparagraph  
7           upon the issuance of an order section  
8           910(c)(1)(A)(i) with respect to that product.”.

9   **SEC. 5903. NO EXEMPTIONS ALLOWED FOR ENDS.**

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

12               (1) in paragraph (2), by adding at the end the  
13          following:

14               “(C) APPLICATION TO ENDS.—Notwith-  
15               standing clauses (i) and (ii) of subparagraphs  
16               (A) and (B), beginning on the date that is 60  
17               days after the date of the enactment of this  
18               subparagraph—

19                       “(i) electronic nicotine delivery sys-  
20                       tems are deemed to be not substantially  
21                       equivalent to any predicate tobacco prod-  
22                       uct; and

23                       “(ii) the requirement for premarket  
24                       review under subparagraph (A) shall apply

1 to a tobacco product that is an electronic  
2 nicotine delivery system.”; and  
3 (2) in paragraph (3)(C)—  
4 (A) by striking “equivalent to a predicate”  
5 and inserting the following: “equivalent—  
6 “(A) to a predicate”;  
7 (B) by striking “adulterated.” and insert-  
8 ing “adulterated; or”; and  
9 (C) by adding at the end the following:  
10 “(B) beginning on the date that is 60 days  
11 after the date of the enactment of this subpara-  
12 graph, if the tobacco product is an electronic  
13 nicotine delivery system.”.

