

116TH CONGRESS
1ST SESSION

S. _____

To establish standards for the design of electronic nicotine delivery systems.

IN THE SENATE OF THE UNITED STATES

Mr. MERKLEY (for himself, Ms. MURKOWSKI, Mr. DURBIN, Mr. BLUMENTHAL, and Mrs. SHAHEEN) introduced the following bill; which was read twice and referred to the Committee on _____

A BILL

To establish standards for the design of electronic nicotine delivery systems.

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 “E-Cigarette Device
5 Standards Act of 2019”.

6 **SEC. 2. STANDARDS RELATING TO ELECTRONIC NICOTINE**
7 **DELIVERY SYSTEMS.**

8 (a) ESTABLISHMENT OF STANDARDS.—

9 (1) IN GENERAL.—Section 907(a) of the Fed-
10 eral Food, Drug, and Cosmetic Act (21 U.S.C.

1 387g(a)) is amended by adding at the end the fol-
2 lowing:

3 “(7) STANDARDS RELATING TO ELECTRONIC
4 NICOTINE DELIVERY SYSTEMS.—The Secretary shall
5 establish standards regarding the design of elec-
6 tronic nicotine delivery systems that, at a minimum,
7 prevent consumers from modifying or adding any
8 substances to electronic nicotine delivery systems
9 (including their components or parts) in a way that
10 is not intended by the manufacturer.”.

11 (2) TIMING.—The Secretary of Health and
12 Human Services shall—

13 (A) not later than 180 days after the date
14 of enactment of this Act, issue proposed regula-
15 tions to carry out the amendment made by
16 paragraph (1); and

17 (B) not later than 1 year after the date of
18 enactment of this Act, issue final regulations to
19 carry out such amendment.

20 (b) DEFINITION.—Section 900 of the Federal Food,
21 Drug, and Cosmetic Act (21 U.S.C. 387) is amended—

22 (1) by redesignating paragraphs (8) through
23 (22) as paragraphs (9) through (23), respectively;
24 and

1 (2) by inserting after paragraph (7) the fol-
2 lowing:

3 “(8) ELECTRONIC NICOTINE DELIVERY SYS-
4 TEM.—

5 “(A) IN GENERAL.—The term ‘electronic
6 nicotine delivery system’ means any electronic
7 device that delivers nicotine, flavor, or another
8 substance via an aerosolized solution to the user
9 inhaling from the device (including e-cigarettes,
10 e-hookah, e-cigars, vapes, vape pens, advanced
11 refillable personal vaporizers, and electronic
12 pipes) and any component, liquid, part, or ac-
13 cessory of such a device, whether or not sold
14 separately, and includes components and parts
15 of the electronic nicotine delivery system.

16 “(B) COMPONENT OR PART.—With respect
17 to an electronic nicotine delivery system, the
18 terms ‘component’ and ‘part’—

19 “(i) mean any software or assembly of
20 materials intended or reasonably ex-
21 pected—

22 “(I) to alter or affect the tobacco
23 product’s performance, composition,
24 constituents or characteristics; or

1 “(II) to be used with or for the
2 human consumption of a tobacco
3 product;

4 “(ii) exclude anything that is an ac-
5 cessory of a tobacco product; and

6 “(iii) include e-liquids; atomizers; bat-
7 teries (with or without variable voltage);
8 cartomizers (atomizer plus replaceable
9 fluid-filled cartridge); digital display or
10 lights to adjust settings; clearomisers, tank
11 systems, flavors, vials that contain e-liq-
12 uids, and programmable software, flavor
13 enhancers and the vials in which such fla-
14 vor enhancers are contained; hose cooling
15 attachments; water filtration base additives
16 (including flavored additives); flavored
17 waterpipe tobacco charcoals and the wrap-
18 pers or boxes that contain the charcoals;
19 and bowls, valves, hoses, and heads.”.

20 (c) CONFORMING AMENDMENT.—Section 9(1) of the
21 Comprehensive Smokeless Tobacco Health Education Act
22 of 1986 (15 U.S.C. 4408(1)) is amended by striking “sec-
23 tion 900(18)” and inserting “section 900(19)”.