II

116TH CONGRESS
1ST SESSION

S. 2536

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

IN THE SENATE OF THE UNITED STATES

SEPTEMBER 24, 2019

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 Health, Education, Labor, and Pensions

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A BILL

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

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''E-Cigarette Device Standards Act of 2019''.

SEC. 2. STANDARDS RELATING TO ELECTRONIC NICOTINE DELIVERY SYSTEMS.

(a) ESTABLISHMENT OF STANDARDS.—

(1) IN GENERAL.—Section 907(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C.

387g(a)) is amended by adding at the end the following:

''(7) STANDARDS RELATING TO ELECTRONIC NICOTINE DELIVERY SYSTEMS.—The Secretary shall establish standards regarding the design of electronic nicotine delivery systems that, at a minimum, prevent consumers from modifying or adding any substances to electronic nicotine delivery systems (including their components or parts) in a way that is not intended by the manufacturer.''.

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

(A) not later than 180 days after the date of enactment of this Act, issue proposed regulations to carry out the amendment made by paragraph (1); and

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

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

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

(2) by inserting after paragraph (7) the following:

''(8) ELECTRONIC NICOTINE DELIVERY SYSTEM.—

''(A) IN GENERAL.—The term 'electronic nicotine delivery system' means any electronic device that delivers nicotine, flavor, or another substance via an aerosolized solution to the user inhaling from the device (including e-cigarettes, e-hookah, e-cigars, vapes, vape pens, advanced refillable personal vaporizers, and electronic pipes) and any component, liquid, part, or accessory of such a device, whether or not sold separately, and includes components and parts of the electronic nicotine delivery system.

''(B) COMPONENT OR PART.—With respect to an electronic nicotine delivery system, the terms 'component' and 'part'—

''(i) mean any software or assembly of materials intended or reasonably expected—

''(I) to alter or affect the tobacco product's performance, composition, constituents or characteristics; or

"(II) to be used with or for the human consumption of a tobacco product;

"(ii) exclude anything that is an accessory of a tobacco product; and

"(iii) include e-liquids; atomizers; batteries (with or without variable voltage); cartomizers (atomizer plus replaceable fluid-filled cartridge); digital display or lights to adjust settings; clearomisers, tank systems, flavors, vials that contain e-liquids, and programmable software, flavor enhancers and the vials in which such flavor enhancers are contained; hose cooling attachments; water filtration base additives (including flavored additives); flavored waterpipe tobacco charcoals and the wrappers or boxes that contain the charcoals; and bowls, valves, hoses, and heads.".

(c) CONFORMING AMENDMENT.—Section 9(1) of the Comprehensive Smokeless Tobacco Health Education Act of 1986 (15 U.S.C. 4408(1)) is amended by striking "section 900(18)" and inserting "section 900(19)".

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