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H. R. 1517

To provide greater clarity in the regulation of electronic nicotine delivery systems, including electronic cigarettes, cigars, cigarillos, pipes, and hookahs, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

MARCH 19, 2015

Ms. SPEIER (for herself, Mr. CÁRDENAS, Mr. DEFAZIO, Mr. HONDA, Mr. RANGEL, and Ms. SCHAKOWSKY) introduced the following bill; which was referred to the Committee on Energy and Commerce

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A BILL

To provide greater clarity in the regulation of electronic nicotine delivery systems, including electronic cigarettes, cigars, cigarillos, pipes, and hookahs, and for other purposes.

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 ''Stop Selling and Marketing to Our Kids E–Cigarettes Act'' or the ''SMOKE Act''.

SEC. 2. FINDINGS; SENSE OF CONGRESS.

(a) FINDINGS.—Congress finds the following:

(1) According to the Food and Drug Administration, because electronic cigarettes have not been fully studied, consumers currently do not know—

(A) the potential risks of electronic cigarettes when used as intended;

(B) how much nicotine or other potentially harmful chemicals are being inhaled during use; or

(C) if there are any benefits associated with using these products.

(2) Use of electronic cigarettes has risen in youth according to a study by the Centers for Disease Control and Prevention that was released in August 2014, which found that in two years, from 2011 to 2013, the percentage of middle and high school students who had ever used electronic cigarettes more than tripled.

(3) According to a policy statement from the American Association for Cancer Research and the American Society of Clinical Oncology published in Clinical Cancer Research in January 2015, ''Electronic nicotine delivery systems may also be harmful, particularly to youth, if they increase the likelihood that nonsmokers or former smokers will use combus-

tible tobacco products or if they discourage smokers from quitting.''.

(4) The New England Journal of Medicine published a study in January 2015 conducted by Portland State University researchers which revealed that e-cigarette vapor can contain hidden formaldehyde at levels five to 15 times higher than regular cigarettes. The International Agency for Research on Cancer has classified formaldehyde in the riskiest category, saying it causes cancer in humans.

(5) The 2014 Surgeon General's report on smoking, commemorating the 50th anniversary of the first Surgeon General report on smoking and health, concludes that nicotine adversely affect maternal and fetal health during pregnancy contributing to multiple adverse outcomes such as preterm delivery and stillbirth. Overall, that exposure to nicotine during fetal development has lasting adverse consequences for brain development. Moreover, evidence suggests that nicotine exposure during adolescence may also have lasting consequences on the developing brain.

(6) Marketing of electronic cigarettes to youth is occurring in the form of advertising using car-

toons and sponsorships of events popular with youth such as concerts and sporting events.

(7) According to the Centers for Disease Control and Prevention, Poison Control Centers reported a rapid increase in electronic cigarette-related exposures, of which 51.1 percent were among young children. Electronic cigarette exposure calls per month increased from one in September 2010 to 215 in February 2014.

(8) Due to the lack of long-term studies, we do not know the viability of claims that electronic cigarettes help to lessen dependence on regular cigarettes.

(9) According to a paper entitled ''E–Cigarettes: A Scientific Review'' published in the American Heart Association's peer-reviewed journal Circulation, electronic cigarettes contain particles small enough to get into the lungs and then cross into the systemic circulation just like cigarettes. Therefore, electronic cigarettes do not only produce ''water vapor'' as is claimed in the marketing of these products. Furthermore, the particle size distribution and number of particles delivered by electronic cigarettes are similar to those contained in conventional cigarettes. There is already strong evidence that fre-

quent low or short-term levels of exposure to these types of particles from tobacco smoke or air pollution can contribute to health problems such as the increased risk of cardiovascular and respiratory disease and death.

(10) The e-liquids used in electronic cigarettes may be toxic if ingested or absorbed through the skin at relatively low quantities. The lack of childproof containers makes this even more of a safety risk for children.

(b) SENSE OF CONGRESS.—It is the sense of Congress that—

(1) the Food and Drug Administration—

(A) has been authorized to regulate the sale, labeling, packaging, marketing, and advertising of electronic nicotine delivery systems and e-liquids since the enactment of the Family Smoking Prevention and Tobacco Control Act on June 22, 2009; and

(B) should exercise this authority; and

(2) the Federal Trade Commission should prohibit the advertising, promoting, and marketing in commerce of electronic nicotine delivery systems and e-liquids to children as an unfair or deceptive act or

practice, in order to protect the health of the youth of the United States.

SEC. 3. FDA REGULATION OF ELECTRONIC NICOTINE DELIVERY SYSTEMS AND E-LIQUIDS.

(a) DEFINITIONS.—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 (10) through (24), respectively; and

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

"(8) ELECTRONIC NICOTINE DELIVERY SYSTEM.—The term 'electronic nicotine delivery system'—

"(A) means any product, the use of which may resemble smoking, that provides an inhalable dose of nicotine by delivery of a vaporized solution, including any such product that is marketed as an electronic cigarette, cigar, cigarillo, pipe, or hookah; and

"(B) includes any component, part, or paraphernalia of such a product, including cartridges, cartomizers, e-liquid, smoke juice, tips, atomizers, batteries, and chargers, whether or

not the component, part, or paraphernalia is sold separately.

"(9) E-LIQUID.—The term 'e-liquid' means a solution that contains nicotine, flavorings, or other chemicals that is intended to be used to produce an inhaled vapor from an electronic nicotine delivery system.".

(b) REGULATION AS TOBACCO PRODUCTS UNDER FEDERAL FOOD, DRUG, AND COSMETIC ACT.—Section 901(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 387a(b)) is amended by striking "This chapter shall apply to all cigarettes," and inserting "This chapter shall apply to all cigarettes, electronic nicotine delivery systems, e-liquids,".

(c) REGULATION AS CIGARETTES UNDER FEDERAL CIGARETTE LABELING AND ADVERTISING ACT.—Section 3(1) of the Federal Cigarette Labeling and Advertising Act (15 U.S.C. 1332(1)) is amended—

(1) in subparagraph (A), by striking "and" at the end;

(2) in subparagraph (B), by striking the period at the end and inserting "; and"; and

(3) by adding at the end the following:

"(C) any electronic nicotine delivery system (as such term is defined in section 900 of the Federal Food, Drug, and Cosmetic Act).".

(d) CHARACTERIZING FLAVORS.—

(1) STUDY.—By not later than one year after the date of enactment of this Act, the Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs, shall complete a study on—

(A) any purported health benefits associated with flavorings for electronic nicotine delivery systems and e-liquids, including whether any such flavorings help adults to quit smoking; and

(B) whether any such flavorings would appeal to children and increase their likelihood to use electronic nicotine delivery systems or e-liquids.

(2) CONSIDERATION OF TOBACCO PRODUCT STANDARD.—Upon completion of the study under paragraph (1), the Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs, shall consider whether to adopt a tobacco product standard under section 907(a)(3) of the Federal Food, Drug, and Cosmetic Act (21

U.S.C. 387g(a)(3)) prohibiting or restricting the use of flavorings in electronic nicotine delivery systems and e-liquids.

(e) CHILD-PROOF PACKAGING.—Not later than 1 year after the date of enactment of this Act, the Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs, shall promulgate a final tobacco product standard under section 907 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 387g) requiring child-proof packaging for electronic nicotine delivery systems and e-liquids.

(f) DOSAGE LIMITS.—Not later than 1 year after the date of enactment of this Act, the Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs—

(1) shall promulgate a final tobacco product standard under section 907 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 387g) establishing dosage limits for electronic nicotine delivery systems and e-liquids that are adequate for the majority of smokers using an electronic nicotine delivery system as a substitute to smoking; and

(2) may include in such tobacco product standard an exception allowing consumers to access electronic nicotine delivery systems and e-liquids con-

taining nicotine in excess of the dosage limit established under paragraph (1) pursuant to a prescription.

(g) CONCENTRATIONS.—Not later than 1 year after the date of enactment of this Act, the Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs—

(1) shall promulgate a final tobacco product standard under section 907 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 387g) establishing for e-liquids maximum levels for the concentration of nicotine, and establishing labeling requirements with respect to the concentration of nicotine, that are adequate for the majority of smokers using an electronic nicotine delivery system as a substitute to smoking; and

(2) may include in such tobacco product standard an exception allowing consumers to access e-liquids containing nicotine in excess of the dosage limit established under paragraph (1) pursuant to a prescription.

(h) REGULATIONS.—The Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs, shall make such changes to the final rule promulgated under section 102 of the Family Smoking

Prevention and Tobacco Control Act (21 U.S.C. 387a–1) (or any successor regulation) as may be necessary to implement the provisions of this section and the amendments made by this section.

SEC. 4. PROHIBITION ON MARKETING OF ELECTRONIC NICOTINE DELIVERY SYSTEMS TO CHILDREN.

(a) PROHIBITION.—No person may advertise, promote, or market in commerce an electronic nicotine delivery system or an e-liquid in a manner that the person knows or should know will have the effect of increasing the use of an electronic nicotine delivery system or e-liquid by a child.

(b) ENFORCEMENT BY FEDERAL TRADE COMMISSION.—

(1) UNFAIR OR DECEPTIVE ACT OR PRACTICE.—A violation of subsection (a) shall be treated as a violation of a rule defining an unfair or deceptive act or practice described under section 18(a)(1)(B) of the Federal Trade Commission Act (15 U.S.C. 57a(a)(1)(B)).

(2) POWERS OF COMMISSION.—

(A) IN GENERAL.—The Federal Trade Commission shall enforce this section in the same manner, by the same means, and with the same jurisdiction, powers, and duties as though

all applicable terms and provisions of the Federal Trade Commission Act (15 U.S.C. 41 et seq.) were incorporated into and made a part of this section.

(B) PRIVILEGES AND IMMUNITIES.—Any person who violates this section shall be subject to the penalties and entitled to the privileges and immunities provided in the Federal Trade Commission Act (15 U.S.C. 41 et seq.).

(C) RULEMAKING.—The Federal Trade Commission may promulgate standards and rules to carry out this section in accordance with section 553 of title 5, United States Code.

(c) ENFORCEMENT BY STATES.—

(1) IN GENERAL.—In any case in which the attorney general of a State has reason to believe that an interest of the residents of the State has been or is threatened or adversely affected by the engagement of any person subject to subsection (a) in a practice that violates such subsection, the attorney general of the State may, as parens patriae, bring a civil action on behalf of the residents of the State in an appropriate district court of the United States—

(A) to enjoin further violation of such subsection by such person;

(B) to compel compliance with such subsection;

(C) to obtain damages, restitution, or other compensation on behalf of such residents;

(D) to obtain such other relief as the court considers appropriate; or

(E) to obtain civil penalties in the amount determined under paragraph (2).

(2) CIVIL PENALTIES.—

(A) CALCULATION.—For purposes of imposing a civil penalty under paragraph (1)(E) with respect to a person who violates subsection (a), the amount determined under this paragraph is the amount calculated by multiplying the number of days that the person is not in compliance with subsection (a) by an amount not greater than $16,000.

(B) ADJUSTMENT FOR INFLATION.—Beginning on the date on which the Bureau of Labor Statistics first publishes the Consumer Price Index after the date that is 1 year after the date of the enactment of this Act, and annually thereafter, the amounts specified in sub-

paragraph (A) shall be increased by the percentage increase in the Consumer Price Index published on that date from the Consumer Price Index published the previous year.

(3) RIGHTS OF FEDERAL TRADE COMMISSION.—

(A) NOTICE TO FEDERAL TRADE COMMISSION.—

(i) IN GENERAL.—Except as provided in clause (iii), the attorney general of a State shall notify the Federal Trade Commission in writing that the attorney general intends to bring a civil action under paragraph (1) not later than 10 days before initiating the civil action.

(ii) CONTENTS.—The notification required by clause (i) with respect to a civil action shall include a copy of the complaint to be filed to initiate the civil action.

(iii) EXCEPTION.—If it is not feasible for the attorney general of a State to provide the notification required by clause (i) before initiating a civil action under paragraph (1), the attorney general shall notify

the Federal Trade Commission immediately upon instituting the civil action.

(B) INTERVENTION BY FEDERAL TRADE COMMISSION.—The Federal Trade Commission may—

(i) intervene in any civil action brought by the attorney general of a State under paragraph (1); and

(ii) upon intervening—

(I) be heard on all matters arising in the civil action; and

(II) file petitions for appeal of a decision in the civil action.

(4) INVESTIGATORY POWERS.—Nothing in this subsection may be construed to prevent the attorney general of a State from exercising the powers conferred on the attorney general by the laws of the State to conduct investigations, to administer oaths or affirmations, or to compel the attendance of witnesses or the production of documentary or other evidence.

(5) PREEMPTIVE ACTION BY FEDERAL TRADE COMMISSION.—If the Federal Trade Commission institutes a civil action or an administrative action with respect to a violation of subsection (a), the at-

torney general of a State may not, during the pendency of such action, bring a civil action under paragraph (1) against any defendant named in the complaint of the Commission for the violation with respect to which the Commission instituted such action.

(6) VENUE; SERVICE OF PROCESS.—

(A) VENUE.—Any action brought under paragraph (1) may be brought in—

(i) the district court of the United States that meets applicable requirements relating to venue under section 1391 of title 28, United States Code; or

(ii) another court of competent jurisdiction.

(B) SERVICE OF PROCESS.—In an action brought under paragraph (1), process may be served in any district in which the defendant—

(i) is an inhabitant; or

(ii) may be found.

(7) ACTIONS BY OTHER STATE OFFICIALS.—

(A) IN GENERAL.—In addition to civil actions brought by attorneys general under paragraph (1), any other officer of a State who is authorized by the State to do so may bring a

civil action under paragraph (1), subject to the same requirements and limitations that apply under this subsection to civil actions brought by attorneys general.

(B) SAVINGS PROVISION.—Nothing in this subsection may be construed to prohibit an authorized official of a State from initiating or continuing any proceeding in a court of the State for a violation of any civil or criminal law of the State.

(d) CONSTRUCTION.—Nothing in this section shall be construed to limit or diminish the authority of the Food and Drug Administration to regulate the marketing of electronic nicotine delivery systems, including the marketing of electronic nicotine delivery systems to children.

(e) RELATION TO STATE LAW.—This section shall not be construed as superseding, altering, or affecting any provision of law of a State, except to the extent that such provision of law is inconsistent with the provisions of this section, and then only to the extent of the inconsistency.

SEC. 5. DEFINITIONS.

In this Act:

(1) ELECTRONIC NICOTINE DELIVERY SYSTEM.—The term ''electronic nicotine delivery system''—

(A) means any product, the use of which may resemble smoking, that provides an inhalable dose of nicotine by delivery of a vaporized solution, including any such product that is marketed as an electronic cigarette, cigar, cigarillo, pipe, or hookah; and

(B) includes any component, part, or paraphernalia of such a product, including cartridges, cartomizers, e-liquid, smoke juice, tips, atomizers, batteries, and chargers, whether or not the component, part, or paraphernalia is sold separately.

(2) E-LIQUID.—The term ''e-liquid'' means a solution that contains nicotine, flavorings, or other chemicals that is intended to be used to produce an inhaled vapor from an electronic nicotine delivery system.

(3) CHILD.—The term ''child'' means an individual who is under the age of 18 years.

(4) COMMERCE.—The term ''commerce'' has the meaning given such term in section 4 of the Federal Trade Commission Act (15 U.S.C. 44).

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