

113TH CONGRESS
2D SESSION

H. R. 5010

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

JUNE 26, 2014

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

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.

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 “Stop Selling and Mar-
5 keting to Our Kids E-Cigarettes Act” or the “SMOKE
6 Act”.

7 **SEC. 2. FINDINGS; SENSE OF CONGRESS.**

8 (a) FINDINGS.—Congress finds the following:

1 (1) According to the Food and Drug Adminis-
2 tration, because electronic cigarettes have not been
3 fully studied, consumers currently do not know—

4 (A) the potential risks of electronic ciga-
5 rettes when used as intended;

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

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

11 (2) Use of electronic cigarettes has risen in
12 youth according to a study by the Centers for Dis-
13 ease Control and Prevention that was released in
14 September 2013, which found that in one year, from
15 2011 to 2012, the percentage of middle and high
16 school students who had ever used electronic ciga-
17 rettes more than doubled.

18 (3) Electronic cigarette use may lead children
19 to become addicted to nicotine and could be a gate-
20 way to various tobacco products.

21 (4) Additionally, according to the Centers for
22 Disease Control and Prevention, 1 in 5 middle
23 school students who reported ever using electronic
24 cigarettes had never tried conventional cigarettes.

1 (5) Marketing of electronic cigarettes to youth
2 is occurring in the form of advertising using car-
3 toons and sponsorships of events popular with youth
4 such as concerts and sporting events.

5 (6) According to the Centers for Disease Con-
6 trol and Prevention, Poison Control Centers reported
7 rapid increase in electronic cigarette-related expo-
8 sures, of which 51.1 percent were among young chil-
9 dren. Electronic cigarette exposure calls per month
10 increased from one in September 2010 to 215 in
11 February 2014.

12 (7) Due to the lack of long-term studies, we do
13 not know the viability of claims that electronic ciga-
14 rettes help to lessen dependence on regular ciga-
15 rettes.

16 (8) According to a paper entitled “E-Ciga-
17 rettes: A Scientific Review” published in the Amer-
18 ican Heart Association’s peer-reviewed journal Cir-
19 culation, electronic cigarettes contain particles small
20 enough to get into the lungs and then cross into the
21 systemic circulation just like cigarettes. Therefore,
22 electronic cigarettes do not only produce “water
23 vapor” as is claimed in the marketing of these prod-
24 ucts. Furthermore, the particle size distribution and
25 number of particles delivered by electronic cigarettes

1 are similar to those contained in conventional ciga-
2 rettes. There is already strong evidence that fre-
3 quent low or short-term levels of exposure to these
4 types of particles from tobacco smoke or air pollu-
5 tion can contribute to health problems such as the
6 increased risk of cardiovascular and respiratory dis-
7 ease and death.

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

13 (b) SENSE OF CONGRESS.—It is the sense of Con-
14 gress that—

15 (1) the Food and Drug Administration—

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

22 (B) should exercise this authority; and

23 (2) the Federal Trade Commission should pro-
24 hibit the advertising, promoting, and marketing in
25 commerce of electronic nicotine delivery systems and

1 e-liquids to children as an unfair or deceptive act or
2 practice, in order to protect the health of the youth
3 of the United States.

4 **SEC. 3. FDA REGULATION OF ELECTRONIC NICOTINE DE-**
5 **LIVERY SYSTEMS AND E-LIQUIDS.**

6 (a) DEFINITIONS.—Section 900 of the Federal Food,
7 Drug, and Cosmetic Act (21 U.S.C. 387) is amended—

8 (1) by redesignating paragraphs (8) through
9 (22) as paragraphs (10) through (24), respectively;
10 and

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

13 “(8) ELECTRONIC NICOTINE DELIVERY SYS-
14 TEM.—The term ‘electronic nicotine delivery sys-
15 tem’—

16 “(A) means any product, the use of which
17 may resemble smoking, that provides an
18 inhalable dose of nicotine by delivery of a va-
19 porized solution, including any such product
20 that is marketed as an electronic cigarette,
21 cigar, cigarillo, pipe, or hookah; and

22 “(B) includes any component, part, or par-
23 aphernalia of such a product, including car-
24 tridges, cartomizers, e-liquid, smoke juice, tips,
25 atomizers, batteries, and chargers, whether or

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

3 “(9) E-LIQUID.—The term ‘e-liquid’ means a
4 solution that contains nicotine, flavorings, or other
5 chemicals that is intended to be used to produce an
6 inhaled vapor from an electronic nicotine delivery
7 system.”.

8 (b) REGULATION AS TOBACCO PRODUCTS UNDER
9 FEDERAL FOOD, DRUG, AND COSMETIC ACT.—Section
10 901(b) of the Federal Food, Drug, and Cosmetic Act (21
11 U.S.C. 387a(b)) is amended by striking “This chapter
12 shall apply to all cigarettes,” and inserting “This chapter
13 shall apply to all cigarettes, electronic nicotine delivery
14 systems, e-liquids,”.

15 (c) REGULATION AS CIGARETTES UNDER FEDERAL
16 CIGARETTE LABELING AND ADVERTISING ACT.—Section
17 3(1) of the Federal Cigarette Labeling and Advertising
18 Act (15 U.S.C. 1332(1)) is amended—

19 (1) in subparagraph (A), by striking “and” at
20 the end;

21 (2) in subparagraph (B), by striking the period
22 at the end and inserting “; and”; and

23 (3) by adding at the end the following:

1 “(C) any electronic nicotine delivery sys-
2 tem (as such term is defined in section 900 of
3 the Federal Food, Drug, and Cosmetic Act).”.

4 (d) CHARACTERIZING FLAVORS.—

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

10 (A) any purported health benefits associ-
11 ated with flavorings for electronic nicotine deliv-
12 ery systems and e-liquids, including whether
13 any such flavorings help adults to quit smoking;
14 and

15 (B) whether any such flavorings would ap-
16 peal to children and increase their likelihood to
17 use electronic nicotine delivery systems or e-liq-
18 uids.

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

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

4 (e) CHILD-PROOF PACKAGING.—Not later than 1
5 year after the date of enactment of this Act, the Secretary
6 of Health and Human Services, acting through the Com-
7 missioner of Food and Drugs, shall promulgate a final to-
8 bacco product standard under section 907 of the Federal
9 Food, Drug, and Cosmetic Act (21 U.S.C. 387g) requiring
10 child-proof packaging for electronic nicotine delivery sys-
11 tems and e-liquids.

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

16 (1) shall promulgate a final tobacco product
17 standard under section 907 of the Federal Food,
18 Drug, and Cosmetic Act (21 U.S.C. 387g) estab-
19 lishing dosage limits for electronic nicotine delivery
20 systems and e-liquids that are adequate for the ma-
21 jority of smokers using an electronic nicotine deliv-
22 ery system as a substitute to smoking; and

23 (2) may include in such tobacco product stand-
24 ard an exception allowing consumers to access elec-
25 tronic nicotine delivery systems and e-liquids con-

1 taining nicotine in excess of the dosage limit estab-
2 lished under paragraph (1) pursuant to a prescrip-
3 tion.

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

8 (1) shall promulgate a final tobacco product
9 standard under section 907 of the Federal Food,
10 Drug, and Cosmetic Act (21 U.S.C. 387g) estab-
11 lishing for e-liquids maximum levels for the con-
12 centration of nicotine, and establishing labeling re-
13 quirements with respect to the concentration of nico-
14 tine, that are adequate for the majority of smokers
15 using an electronic nicotine delivery system as a sub-
16 stitute to smoking; and

17 (2) may include in such tobacco product stand-
18 ard an exception allowing consumers to access e-liq-
19 uids containing nicotine in excess of the dosage limit
20 established under paragraph (1) pursuant to a pre-
21 scription.

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

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

5 **SEC. 4. PROHIBITION ON MARKETING OF ELECTRONIC NIC-**
6 **OTINE DELIVERY SYSTEMS TO CHILDREN.**

7 (a) PROHIBITION.—No person may advertise, pro-
8 mote, or market in commerce an electronic nicotine deliv-
9 ery system or an e-liquid in a manner that the person
10 knows or should know will have the effect of increasing
11 the use of an electronic nicotine delivery system or e-liquid
12 by a child.

13 (b) ENFORCEMENT BY FEDERAL TRADE COMMIS-
14 SION.—

15 (1) UNFAIR OR DECEPTIVE ACT OR PRAC-
16 TICE.—A violation of subsection (a) shall be treated
17 as a violation of a rule defining an unfair or decep-
18 tive act or practice described under section
19 18(a)(1)(B) of the Federal Trade Commission Act
20 (15 U.S.C. 57a(a)(1)(B)).

21 (2) POWERS OF COMMISSION.—

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

1 all applicable terms and provisions of the Fed-
2 eral Trade Commission Act (15 U.S.C. 41 et
3 seq.) were incorporated into and made a part of
4 this section.

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

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

14 (c) ENFORCEMENT BY STATES.—

15 (1) IN GENERAL.—In any case in which the at-
16 torney general of a State has reason to believe that
17 an interest of the residents of the State has been or
18 is threatened or adversely affected by the engage-
19 ment of any person subject to subsection (a) in a
20 practice that violates such subsection, the attorney
21 general of the State may, as *parens patriae*, bring
22 a civil action on behalf of the residents of the State
23 in an appropriate district court of the United
24 States—

1 (A) to enjoin further violation of such sub-
2 section by such person;

3 (B) to compel compliance with such sub-
4 section;

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

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

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

11 (2) CIVIL PENALTIES.—

12 (A) CALCULATION.—For purposes of im-
13 posing a civil penalty under paragraph (1)(E)
14 with respect to a person who violates subsection
15 (a), the amount determined under this para-
16 graph is the amount calculated by multiplying
17 the number of days that the person is not in
18 compliance with subsection (a) by an amount
19 not greater than \$16,000.

20 (B) ADJUSTMENT FOR INFLATION.—Be-
21 ginning on the date on which the Bureau of
22 Labor Statistics first publishes the Consumer
23 Price Index after the date that is 1 year after
24 the date of the enactment of this Act, and an-
25 nually thereafter, the amounts specified in sub-

1 paragraph (A) shall be increased by the per-
2 centage increase in the Consumer Price Index
3 published on that date from the Consumer
4 Price Index published the previous year.

5 (3) RIGHTS OF FEDERAL TRADE COMMIS-
6 SION.—

7 (A) NOTICE TO FEDERAL TRADE COMMIS-
8 SION.—

9 (i) IN GENERAL.—Except as provided
10 in clause (iii), the attorney general of a
11 State shall notify the Federal Trade Com-
12 mission in writing that the attorney gen-
13 eral intends to bring a civil action under
14 paragraph (1) not later than 10 days be-
15 fore initiating the civil action.

16 (ii) CONTENTS.—The notification re-
17 quired by clause (i) with respect to a civil
18 action shall include a copy of the complaint
19 to be filed to initiate the civil action.

20 (iii) EXCEPTION.—If it is not feasible
21 for the attorney general of a State to pro-
22 vide the notification required by clause (i)
23 before initiating a civil action under para-
24 graph (1), the attorney general shall notify

1 the Federal Trade Commission imme-
2 diately upon instituting the civil action.

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

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

9 (ii) upon intervening—

10 (I) be heard on all matters aris-
11 ing in the civil action; and

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

14 (4) INVESTIGATORY POWERS.—Nothing in this
15 subsection may be construed to prevent the attorney
16 general of a State from exercising the powers con-
17 ferred on the attorney general by the laws of the
18 State to conduct investigations, to administer oaths
19 or affirmations, or to compel the attendance of wit-
20 nesses or the production of documentary or other
21 evidence.

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

1 torney general of a State may not, during the pend-
2 ency of such action, bring a civil action under para-
3 graph (1) against any defendant named in the com-
4 plaint of the Commission for the violation with re-
5 spect to which the Commission instituted such ac-
6 tion.

7 (6) VENUE; SERVICE OF PROCESS.—

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

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

14 (ii) another court of competent juris-
15 diction.

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

19 (i) is an inhabitant; or

20 (ii) may be found.

21 (7) ACTIONS BY OTHER STATE OFFICIALS.—

22 (A) IN GENERAL.—In addition to civil ac-
23 tions brought by attorneys general under para-
24 graph (1), any other officer of a State who is
25 authorized by the State to do so may bring a

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

5 (B) SAVINGS PROVISION.—Nothing in this
6 subsection may be construed to prohibit an au-
7 thorized official of a State from initiating or
8 continuing any proceeding in a court of the
9 State for a violation of any civil or criminal law
10 of the State.

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

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

21 **SEC. 5. DEFINITIONS.**

22 In this Act:

23 (1) ELECTRONIC NICOTINE DELIVERY SYS-
24 TEM.—The term “electronic nicotine delivery sys-
25 tem”—

1 (A) means any product, the use of which
2 may resemble smoking, that provides an
3 inhalable dose of nicotine by delivery of a va-
4 porized solution, including any such product
5 that is marketed as an electronic cigarette,
6 cigar, cigarillo, pipe, or hookah; and

7 (B) includes any component, part, or para-
8 phernalia of such a product, including car-
9 tridges, cartomizers, e-liquid, smoke juice, tips,
10 atomizers, batteries, and chargers, whether or
11 not the component, part, or paraphernalia is
12 sold separately.

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

18 (3) CHILD.—The term “child” means an indi-
19 vidual who is under the age of 18 years.

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

○