

114TH CONGRESS  
1ST SESSION

# 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

---

## 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          August 2014, which found that in two years, from  
15          2011 to 2013, the percentage of middle and high  
16          school students who had ever used electronic ciga-  
17          rettes more than tripled.

18          (3) According to a policy statement from the  
19          American Association for Cancer Research and the  
20          American Society of Clinical Oncology published in  
21          Clinical Cancer Research in January 2015, “Elec-  
22          tronic nicotine delivery systems may also be harmful,  
23          particularly to youth, if they increase the likelihood  
24          that nonsmokers or former smokers will use combus-

1 tible tobacco products or if they discourage smokers  
2 from quitting.”.

3 (4) The New England Journal of Medicine pub-  
4 lished a study in January 2015 conducted by Port-  
5 land State University researchers which revealed  
6 that e-cigarette vapor can contain hidden formalde-  
7 hyde at levels five to 15 times higher than regular  
8 cigarettes. The International Agency for Research  
9 on Cancer has classified formaldehyde in the riskiest  
10 category, saying it causes cancer in humans.

11 (5) The 2014 Surgeon General’s report on  
12 smoking, commemorating the 50th anniversary of  
13 the first Surgeon General report on smoking and  
14 health, concludes that nicotine adversely affect ma-  
15 ternal and fetal health during pregnancy contrib-  
16 uting to multiple adverse outcomes such as preterm  
17 delivery and stillbirth. Overall, that exposure to nico-  
18 tine during fetal development has lasting adverse  
19 consequences for brain development. Moreover, evi-  
20 dence suggests that nicotine exposure during adoles-  
21 cence may also have lasting consequences on the de-  
22 veloping brain.

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

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

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

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

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

1       quent low or short-term levels of exposure to these  
2       types of particles from tobacco smoke or air pollu-  
3       tion can contribute to health problems such as the  
4       increased risk of cardiovascular and respiratory dis-  
5       ease and death.

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

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

13               (1) the Food and Drug Administration—

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

20                       (B) should exercise this authority; and

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

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

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

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

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

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

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

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

21 “(B) includes any component, part, or par-  
22 aphernalia of such a product, including car-  
23 tridges, cartomizers, e-liquid, smoke juice, tips,  
24 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).

○