

116TH CONGRESS
1ST SESSION

H. R. 4624

To amend the Federal Food, Drug, and Cosmetic Act to establish a tobacco product standard prohibiting any e-liquid with a concentration of nicotine higher than 20 milligrams per milliliter, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

OCTOBER 8, 2019

Mr. KRISHNAMOORTHY introduced the following bill; which was referred to the Committee on Energy and Commerce

A BILL

To amend the Federal Food, Drug, and Cosmetic Act to establish a tobacco product standard prohibiting any e-liquid with a concentration of nicotine higher than 20 milligrams per milliliter, 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 “Ending Nicotine De-
5 pendence from Electronic Nicotine Delivery Systems Act
6 of 2019” or the “END ENDS Act of 2019”.

7 **SEC. 2. FINDINGS.**

8 Congress finds as follows:

1 (1) According to the Centers for Disease Con-
2 trol and Prevention (in this section referred to as
3 the “CDC”), the brain keeps developing until ap-
4 proximately age 25, and nicotine exposure can harm
5 the parts of the brain that control attention, learn-
6 ing, mood, and impulse control.

7 (2) Adolescent nicotine use may also increase
8 the risk of future addiction to other drugs.

9 (3) A recent CDC study found that 99 percent
10 of e-cigarettes sold in the United States contain nic-
11 otine.

12 (4) In congressional testimony before the Sub-
13 committee on Economic and Consumer Policy of the
14 Committee on Oversight and Reform of the House
15 of Representatives on September 24, 2019, CDC
16 Principal Deputy Director Anne Schuchat stated
17 that “fourth generation e-cigarette devices” were
18 first sold in 2015 and “use nicotine salts, which can
19 lead to much more available nicotine”.

20 (5) According to Dr. Schuchat’s testimony,
21 fourth generation devices “can cross the blood-brain
22 barrier and lead to potentially more effects on the
23 developing brain in adolescents”. Further, “the very
24 high levels of accessible nicotine and the discreet use
25 of the product” directly link the growing popularity

1 of fourth generation e-cigarette devices to the rise in
2 youth e-cigarette use.

3 (6) Prior to the use of nicotine salts, which are
4 now used in the e-liquids of the most popular e-ciga-
5 rettes, most e-cigarettes contained “freebase nico-
6 tine”. Because freebase nicotine has a much harsher
7 effect on the inhaler, these e-cigarette devices con-
8 tained much less nicotine than devices which contain
9 nicotine salts.

10 (7) The most popular e-cigarette manufactured
11 and sold in the United States, which is considered
12 a “fourth generation device”, most frequently con-
13 tains an “e-liquid” with 59 milligrams per milliliter
14 of nicotine.

15 (8) In response, the European Union, the
16 United Kingdom, and Israel implemented regula-
17 tions to cap the concentration of nicotine in e-ciga-
18 rette e-liquids to 20 milligrams per milliliter.

19 (9) The United Kingdom’s nicotine cap went
20 into effect on May 20, 2017. As youth use sky-
21 rocketed in the United States between 2017 and
22 2018, the percentage of youth e-cigarette users who
23 use more than once a week only rose from 1.2 per-
24 cent to 1.7 percent, and the percentage of youth who

1 use less than weekly decreased from 2.2 percent to
2 1.8 percent.

3 (10) E-cigarettes manufactured and sold in the
4 United States are currently not subject to any nico-
5 tine cap, and e-cigarette manufacturers are per-
6 mitted to design their products to be as addictive as
7 possible.

8 (11) According to the CDC, e-cigarette use rose
9 by 78 percent among high schoolers and 48 percent
10 among middle schoolers between 2017 and 2018.

11 (12) Preliminary results from the CDC’s an-
12 nual National Youth Tobacco Survey published in
13 September 2019 show that 27.5 percent of high
14 school students reported using an e-cigarette in the
15 previous 30 days, up from 20.8 percent in 2018.

16 (13) The CDC, the Food and Drug Administra-
17 tion, the Department of Health and Human Serv-
18 ices, the Surgeon General of the Public Health Serv-
19 ice, and various State and local health authorities
20 have determined the skyrocketing e-cigarette use
21 amongst American youth to be an “epidemic”.

22 **SEC. 3. SENSE OF CONGRESS.**

23 It is the sense of the Congress that—

1 (1) effectively combating the youth e-cigarette
2 epidemic will require the implementation of bold and
3 enduring policy solutions;

4 (2) under the current regulatory framework,
5 American youth have easy access to highly addictive
6 “fourth generation” e-cigarette devices that hook
7 them into a lifelong addiction to nicotine;

8 (3) in order to significantly decrease youth e-
9 cigarette use and to reduce the dangers associated
10 with excessive nicotine inhalation, the Federal Gov-
11 ernment should regulate nicotine levels in e-ciga-
12 rettes in order to make them less addictive and less
13 harmful to youth; and

14 (4) in addition to regulating nicotine levels, the
15 Federal Government should also review other factors
16 related to the composition and function of fourth
17 generation e-cigarettes in order to make them less
18 addictive and appealing to youth, including battery
19 power and design.

20 **SEC. 4. MAXIMUM NICOTINE CONTENT IN E-LIQUIDS.**

21 (a) TOBACCO PRODUCT STANDARD.—Paragraph (1)
22 of section 907(a) of the Federal Food, Drug, and Cosmetic
23 Act (21 U.S.C. 387g(a)) is amended by adding at the end
24 the following new subparagraph:

“(C) NICOTINE CONTENT IN E-LIQUIDS.—

Beginning on the date of enactment of the Ending Nicotine Dependence from Electronic Nicotine Delivery Systems Act of 2019, an e-liquid shall not have a concentration of nicotine higher than—

“(i) 20 milligrams per milliliter; or

“(ii) such lower nicotine concentration as is determined by the Secretary to be minimally addictive or non-addictive.”.

(b) DEFINITIONS.—

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

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

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

“(8) ELECTRONIC NICOTINE DELIVERY SYSTEM.—The term ‘electronic nicotine delivery system’ means a tobacco product that is an 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,

1 vape pens, advanced refillable personal vaporizers,
2 and electronic pipes) and any component, liquid,
3 part, or accessory of such a device, whether or not
4 sold separately.

5 “(9) E-LIQUID.—The term ‘e-liquid’ means any
6 liquid intended for use with an electronic nicotine
7 delivery system.”.

8 (2) CONFORMING AMENDMENT.—Section 9(1)
9 of the Comprehensive Smokeless Tobacco Health
10 Education Act of 1986 (15 U.S.C. 4408(1)) is
11 amended by striking “900(18)” and inserting
12 “900(20)”.

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