

117TH CONGRESS  
1ST SESSION

# H. R. 3051

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.

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## IN THE HOUSE OF REPRESENTATIVES

MAY 7, 2021

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

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## 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 2021” or the “END ENDS Act of 2021”.

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 2020 National Youth To-  
9 bacco Survey, approximately 3,600,000 youths use e-  
10 cigarettes, including 19.6 percent of high school stu-  
11 dents and 4.7 percent of middle school students.

12 (12) Among high school students who smoke e-  
13 cigarettes, nearly 40 percent report using them 20  
14 or more days per month, and nearly one-quarter re-  
15 port using them daily.

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:

1           “(C) NICOTINE CONTENT IN E-LIQUIDS.—  
2           Beginning on the date of enactment of the End-  
3           ing Nicotine Dependence from Electronic Nico-  
4           tine Delivery Systems Act of 2021, an e-liquid  
5           shall not have a concentration of nicotine higher  
6           than—

7                     “(i) 20 milligrams per milliliter; or  
8                     “(ii) such lower nicotine concentration  
9                     as is determined by the Secretary to be  
10                    minimally addictive or non-addictive.”.

11       (b) DEFINITIONS.—

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

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

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

20                    “(8) ELECTRONIC NICOTINE DELIVERY SYS-  
21       TEM.—The term ‘electronic nicotine delivery system’  
22       means a tobacco product that is an electronic device  
23       that delivers nicotine, flavor, or another substance  
24       via an aerosolized solution to the user inhaling from  
25       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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