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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. KRISHNAMOORTHI 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.

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 ''Ending Nicotine Dependence from Electronic Nicotine Delivery Systems Act of 2019'' or the ''END ENDS Act of 2019''.

SEC. 2. FINDINGS.

Congress finds as follows:

(1) According to the Centers for Disease Control and Prevention (in this section referred to as the ''CDC''), the brain keeps developing until approximately age 25, and nicotine exposure can harm the parts of the brain that control attention, learning, mood, and impulse control.

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

(3) A recent CDC study found that 99 percent of e-cigarettes sold in the United States contain nicotine.

(4) In congressional testimony before the Subcommittee on Economic and Consumer Policy of the Committee on Oversight and Reform of the House of Representatives on September 24, 2019, CDC Principal Deputy Director Anne Schuchat stated that ''fourth generation e-cigarette devices'' were first sold in 2015 and ''use nicotine salts, which can lead to much more available nicotine''.

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

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

(6) Prior to the use of nicotine salts, which are now used in the e-liquids of the most popular e-cigarettes, most e-cigarettes contained ''freebase nicotine''. Because freebase nicotine has a much harsher effect on the inhaler, these e-cigarette devices contained much less nicotine than devices which contain nicotine salts.

(7) The most popular e-cigarette manufactured and sold in the United States, which is considered a ''fourth generation device'', most frequently contains an ''e-liquid'' with 59 milligrams per milliliter of nicotine.

(8) In response, the European Union, the United Kingdom, and Israel implemented regulations to cap the concentration of nicotine in e-cigarette e-liquids to 20 milligrams per milliliter.

(9) The United Kingdom's nicotine cap went into effect on May 20, 2017. As youth use skyrocketed in the United States between 2017 and 2018, the percentage of youth e-cigarette users who use more than once a week only rose from 1.2 percent to 1.7 percent, and the percentage of youth who

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

(10) E-cigarettes manufactured and sold in the United States are currently not subject to any nicotine cap, and e-cigarette manufacturers are permitted to design their products to be as addictive as possible.

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

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

(13) The CDC, the Food and Drug Administration, the Department of Health and Human Services, the Surgeon General of the Public Health Service, and various State and local health authorities have determined the skyrocketing e-cigarette use amongst American youth to be an ''epidemic''.

SEC. 3. SENSE OF CONGRESS.

It is the sense of the Congress that—

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

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

(3) in order to significantly decrease youth e-cigarette use and to reduce the dangers associated with excessive nicotine inhalation, the Federal Government should regulate nicotine levels in e-cigarettes in order to make them less addictive and less harmful to youth; and

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

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

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

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

''(9) E-LIQUID.—The term 'e-liquid' means any liquid intended for use with an electronic nicotine delivery system.''.

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

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