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116TH CONGRESS
1ST SESSION

H. R. 2339

To amend the Federal Food, Drug, and Cosmetic Act with respect to the sale and marketing of tobacco products, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

APRIL 18, 2019

Mr. PALLONE (for himself and Ms. SHALALA) 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 with respect to the sale and marketing of tobacco products, 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 ''Reversing the Youth Tobacco Epidemic Act of 2019''.

SEC. 2. TABLE OF CONTENTS.

The table of contents of this Act is as follows:

TITLE I—FOOD AND DRUG ADMINISTRATION

SEC. 101. CIGARETTE GRAPHIC HEALTH WARNINGS.

(a) ISSUANCE DEADLINES.—Not later than 12 months after the date of enactment of this Act, the Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs, shall publish a final rule pursuant to section 4(d) of the Federal Cigarette Labeling and Advertising Act (15 U.S.C. 1333(d)).

(b) CONFORMING CHANGE.—Section 4(d) of the Federal Cigarette Labeling and Advertising Act (15 U.S.C. 1333(d)) is amended by striking ''Not later than 24 months after the date of enactment of the Family Smoking Prevention and Tobacco Control Act, the Secretary'' and inserting ''The Secretary''.

SEC. 102. ADVERTISING AND SALES PARITY FOR ALL DEEMED TOBACCO PRODUCTS.

(a) IN GENERAL.—Not later than 1 year after the date of enactment of this Act, the Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs, shall promulgate a final rule amending

part 1140 of subchapter K of title 21, Code of Federal Regulations—

(1) to apply the provisions of such part 1140 to all tobacco products to which chapter IX of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 387a et seq.) applies pursuant to section 901(b) of such Act (21 U.S.C. 387a(b)), as amended by section 103(a) of this Act; and

(2) to make such changes as may be necessary for consistency with the amendments made by section 103 of this Act.

(b) EFFECTIVE DATE.—The final rule required by subsection (a) shall take effect on the date that is 2 years after the date of enactment of this Act.

SEC. 103. REDUCING CHILD AND ADOLESCENT NICOTINE ADDICTION.

(a) APPLICABILITY TO ALL TOBACCO PRODUCTS.—

(1) IN GENERAL.—Subsection (b) of section 901 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 387a) is amended to read as follows:

''(b) APPLICABILITY.—This chapter shall apply to all tobacco products.''.

(2) RULE OF CONSTRUCTION.—Paragraph (1) and the amendment made thereby shall not be construed to limit the applicability of chapter IX of the

Federal Food, Drug, and Cosmetic Act (21 U.S.C. 387a et seq.) to—

(A) products that were listed in section 901(b) of such Act as in effect on the day before the date of enactment of this Act; and

(B) products that were deemed by regulation to be subject to such chapter pursuant to section 901(b) of such Act as in effect on the day before the date of enactment of this Act.

(b) MINIMUM AGE RESTRICTIONS.—Section 906(d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 387f(d)) is amended by striking paragraph (3) and inserting the following:

''(3) MINIMUM AGE RESTRICTIONS.—

''(A) RESTRICTION.—It shall be unlawful for any retailer, manufacturer, distributor, third-party marketplace, or any other commercial entity to sell a tobacco product to any person younger than 21 years of age.

''(B) AGE VERIFICATION.—To ensure compliance with subparagraph (A), a retailer shall, at a minimum, verify by means of a government-issued photographic identification the age of the individual purchasing the product as prescribed in—

"(i) subpart B of part 1140 of subchapter K of title 21, Code of Federal Regulations; and

"(ii) successor regulations, including the regulation required by section 102 of the Reversing the Youth Tobacco Epidemic Act of 2019 and any applicable regulation imposing restrictions pursuant to paragraph (1).

"(C) NON-PREEMPTION.—Subparagraphs (A) and (B) shall not be construed to limit the authority of a State or political subdivision of a State, or the government of an Indian tribe, as such authority is described in section 916.

"(D) REGULATIONS.—Not later than 180 days after the date of enactment of the Reversing the Youth Tobacco Epidemic Act of 2019, the Secretary shall promulgate a final regulation to implement and enforce subparagraphs (A) and (B).

"(E) TIMING.—Subparagraphs (A) and (B) shall take effect on the date that is 180 days after the date of enactment of the Reversing the Youth Tobacco Epidemic Act of 2019, regardless of whether the Secretary has promul-

gated the final regulations required by subparagraph (D).''.

(c) PROHIBITION AGAINST REMOTE RETAIL SALES.—Paragraph (4) of section 906(d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 387f(d)) is amended to read as follows:

''(4) PROHIBITION AGAINST REMOTE RETAIL SALES.—Not later than 2 years after the date of enactment of the Reversing the Youth Tobacco Epidemic Act of 2019, the Secretary shall promulgate a final regulation under paragraph (1) prohibiting the retail sale of all tobacco products, including electronic nicotine delivery systems and electronic nicotine delivery system accessories, other than retail sales through a direct, face-to-face exchange between a retailer and a consumer.''.

(d) PROHIBITING FLAVORING OF TOBACCO PRODUCTS.—

(1) PROHIBITION.—Subparagraph (A) of section 907(a)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 387g(a)(1)) is amended to read as follows:

''(A) SPECIAL RULE.—Beginning on the date that is 1 year after the date of enactment of the Reversing the Youth Tobacco Epidemic

Act of 2019, except as provided in subparagraph (C), a tobacco product or any of its component parts or accessories (including the tobacco, filter, or paper) shall not contain, as a constituent (including a smoke constituent) or additive, an artificial or natural flavor (other than tobacco) that is a characterizing flavor of the tobacco product or tobacco smoke or an herb or spice, including menthol, mint, strawberry, grape, orange, clove, cinnamon, pineapple, vanilla, coconut, licorice, cocoa, chocolate, cherry, or coffee. Nothing in this subparagraph shall be construed to limit the Secretary's authority to take action under this section or other sections of this Act applicable to any artificial or natural flavor, herb, or spice.''.

(2) EXCEPTION.—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) EXCEPTION FOR CHARACTERIZING FLAVORS TO DECREASE SMOKING.—Notwithstanding subparagraph (A), an electronic nicotine delivery system product or any component or part of such a product may contain, as a

constituent (including a smoke constituent) or additive, an artificial or natural flavor or an herb or spice, that is a characterizing flavor of the tobacco product or tobacco smoke so long as the Secretary, in coordination with the Commissioner of Food and Drugs, determines that such characterizing flavor will be appropriate for the protection of public health because it—

''(i) will significantly increase the likelihood of smoking cessation among current users of tobacco products;

''(ii) will not increase the likelihood that individuals who do not use tobacco products, including youth, will start using such products; and

''(iii) will not increase the likelihood of harm to the person using the product.''.

(3) SAVINGS PROVISION.—Section 907(a)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 387g(a)(1)), as in effect on the date of enactment of this Act, shall remain in effect until the amendments made to such section 907(a)(1) by this subsection take effect.

SEC. 104. FEES APPLICABLE TO ALL TOBACCO PRODUCTS.

(a) INCREASE IN TOTAL AMOUNT.—Section 919(b)(1)(K) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 387s(b)(1)(K)) is amended by striking ''$712,000,000'' and inserting ''$812,000,000''.

(b) APPLICATION OF USER FEES TO ALL CLASSES OF TOBACCO PRODUCTS.—Paragraph (2) of section 919(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 387s(b)(2)) is amended to read as follows:

''(2) ALLOCATIONS OF ASSESSMENT BY CLASS OF TOBACCO PRODUCTS.—The total user fees assessed and collected under subsection (a) each fiscal year with respect to each class of tobacco products shall be an amount that is determined pursuant to a formula developed by the Secretary. Such formula shall ensure that the amount of fees collected is increased by the total percentage change that occurred in the Consumer Price Index for all urban consumers (all items; United States city average) for the 12-month period ending June 30 preceding the fiscal year.''.

(c) ALLOCATION OF ASSESSMENT WITHIN EACH CLASS OF TOBACCO PRODUCT.—Section 919(b)(4) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 387s(b)(4)) is amended by striking ''shall be the percentage determined for purposes of allocations under sub-

sections (e) through (h) of section 625 of Public Law 108–357'' and inserting ''shall be the percentage determined by the Secretary''.

(d) CONFORMING AMENDMENTS.—Section 919(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 387s(b)) is amended—

(1) by striking paragraphs (5) and (7); and

(2) by redesignating paragraph (6) as paragraph (5).

(e) APPLICABILITY.—The amendments made by this section apply beginning with fiscal year 2022. Section 919 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 387s), as in effect on the day before the date of enactment of this Act, shall apply with respect to fiscal years preceding fiscal year 2022.

SEC. 105. REGULATION OF PRODUCTS CONTAINING SYNTHETIC NICOTINE.

(a) IN GENERAL.—The Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs, shall—

(1) not later than 1 year after the date of enactment of this Act, issue an interim final rule providing for the regulation of products containing synthetic nicotine under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.); and

(2) not later than 2 years after such date of enactment, issue a final rule providing for such regulation.

(b) SYNTHETIC NICOTINE DEFINED.—In this section, the term ''synthetic nicotine'' means nicotine that is not made or derived from tobacco.

TITLE II—FEDERAL TRADE COMMISSION

SEC. 201. ADVERTISING OF TOBACCO PRODUCTS.

(a) ADVERTISING OF ELECTRONIC NICOTINE DELIVERY SYSTEMS.—

(1) IN GENERAL.—It shall be unlawful—

(A) to market, advertise, or promote any electronic nicotine delivery system in a manner that appeals to an individual under 21 years of age; or

(B) to market, advertise, promote, or endorse, or to compensate any person for the marketing, advertising, promotion, or endorsement of, any electronic nicotine delivery system without clearly disclosing that the communication is an advertisement, unless the communication is unambiguously identifiable as an advertisement.

(2) ENFORCEMENT BY COMMISSION.—

(A) UNFAIR OR DECEPTIVE ACTS OR PRACTICES.—A violation of paragraph (1) shall be treated as a violation of a regulation under section 18(a)(1)(B) of the Federal Trade Commission Act (15 U.S.C. 57a(a)(1)(B)) regarding unfair or deceptive acts or practices.

(B) POWERS OF COMMISSION.—The Commission shall enforce paragraph (1) in the same manner, by the same means, and with the same jurisdiction, powers, and duties as though all applicable terms and provisions of the Federal Trade Commission Act (15 U.S.C. 41 et seq.) were incorporated into and made a part of this Act. Any person who violates such paragraph shall be subject to the penalties and entitled to the privileges and immunities provided in the Federal Trade Commission Act.

(3) ENFORCEMENT BY STATE ATTORNEYS GENERAL.—

(A) IN GENERAL.—If the attorney general of a State has reason to believe a violation of paragraph (1) has occurred or is occurring, the attorney general, in addition to any authority the attorney general may have to bring an action in State court under the law of the State,

may bring a civil action in any court of competent jurisdiction to—

(i) enjoin further such violation by the defendant;

(ii) enforce compliance with such paragraph;

(iii) obtain civil penalties in the same amount as may be obtained by the Commission in a civil action under section 5(m) of the Federal Trade Commission Act (15 U.S.C. 45(m)); or

(iv) obtain damages, restitution, or other compensation on behalf of residents of the State.

(B) NOTICE.—Before filing an action under subparagraph (A), the attorney general of a State shall provide to the Commission a written notice of such action and a copy of the complaint for such action. If the attorney general determines that it is not feasible to provide the notice described in this subparagraph before the filing of the action, the attorney general shall provide written notice of the action and a copy of the complaint to the Commission immediately upon the filing of the action.

(C) AUTHORITY OF FEDERAL TRADE COMMISSION.—

(i) IN GENERAL.—On receiving notice under subparagraph (B) of an action under subparagraph (A), the Commission shall have the right—

(I) to intervene in the action;

(II) upon so intervening, to be heard on all matters arising therein; and

(III) to file petitions for appeal.

(ii) LIMITATION ON STATE ACTION WHILE FEDERAL ACTION IS PENDING.—If the Commission has instituted a civil action for violation of paragraph (1) (referred to in this clause as the ''Federal action''), no attorney general of a State may bring an action under subparagraph (A) during the pendency of the Federal action against any defendant named in the complaint in the Federal action for any violation of such paragraph alleged in such complaint.

(D) RELATIONSHIP WITH STATE-LAW CLAIMS.—

(i) PRESERVATION OF STATE-LAW CLAIMS.—Nothing in this section shall prevent the attorney general of a State from bringing an action under State law for acts or practices that also violate paragraph (1).

(ii) ASSERTION IN SAME CIVIL ACTION.—If the attorney general of a State has authority to bring an action under State law for acts or practices that also violate paragraph (1), the attorney general may assert the State-law claim and the claim for violation of such paragraph in the same civil action.

(E) ACTIONS BY OTHER STATE OFFICIALS.—In addition to civil actions brought by attorneys general under subparagraph (A), any other consumer protection officer of a State who is authorized by the State to do so may bring a civil action under such subparagraph, subject to the same requirements and limitations that apply under this paragraph to civil actions brought by attorneys general.

(4) RULEMAKING AUTHORITY.—The Commission may promulgate regulations under section 553

of title 5, United States Code, to implement paragraph (1).

(b) REPORT TO CONGRESS ON TOBACCO PRODUCT ADVERTISING.—

(1) IN GENERAL.—Not later than 2 years after the date of the enactment of this Act, and annually thereafter, the Commission shall submit to Congress a report relating to each category of products described in paragraph (2) (or a single report a portion of which relates to each such category) that contains the following:

(A) Information on domestic sales and advertising and promotional activity by the manufacturers that have the largest market shares of the product category.

(B) Such recommendations for legislation as the Commission may consider appropriate.

(2) PRODUCT CATEGORIES DESCRIBED.—The categories of products described in this paragraph are the following:

(A) Cigarettes.

(B) Cigars.

(C) Smokeless tobacco.

(D) Electronic nicotine delivery systems.

(c) PRESERVATION OF AUTHORITY.—Nothing in this section may be construed in any way to limit the Commission's authority under any other provision of law.

(d) DEFINITIONS.—In this section:

(1) CIGAR.—The term ''cigar'' means any roll of tobacco wrapped in leaf tobacco or in any substance containing tobacco (other than any roll of tobacco which is a cigarette within the meaning of paragraph (2)).

(2) CIGARETTE.—The term ''cigarette'' has the meaning given such term in section 900 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 387).

(3) COMMISSION.—The term ''Commission'' means the Federal Trade Commission.

(4) ELECTRONIC NICOTINE DELIVERY SYSTEM.—

(A) IN GENERAL.—The term ''electronic nicotine delivery system'' means—

(i) an electronic device that—

(I) converts a mixture containing nicotine or other substances into an aerosol to be inhaled by the user; and

(II) is a tobacco product; or

(ii) a mixture that—

(I) contains nicotine or other substances that can be aerosolized and inhaled by the user; and

(II) is a tobacco product.

(B) EXCLUSION.—The term ''electronic nicotine delivery system'' does not include any product that—

(i) has been approved or otherwise authorized by the Food and Drug Administration for the purpose of sale as a tobacco cessation product or for other therapeutic purposes; and

(ii) is marketed and sold solely for such purpose or purposes.

(5) ENDORSE.—The term ''endorse'' means to communicate an advertising message (including a verbal statement, demonstration, or depiction of the name, signature, likeness, or other identifying personal characteristics of an individual or the name or seal of an organization) that consumers are likely to believe reflects the opinions, beliefs, findings, or experiences of a party other than the sponsoring advertiser, even if the views expressed by such party are identical to those of the sponsoring advertiser.

(6) NICOTINE.—The term ''nicotine'' has the meaning given such term in section 900 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 387).

(7) SMOKELESS TOBACCO.—The term ''smokeless tobacco'' has the meaning given such term in section 900 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 387).

(8) TOBACCO PRODUCT.—The term ''tobacco product'' has the meaning given such term in section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321).

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