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H. R. 2339

[Report No. 116–402]

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

FEBRUARY 21, 2020

Additional sponsors: Mr. RUSH, Ms. LEE of California, Mr. SARBANES, Ms. UNDERWOOD, Ms. BLUNT ROCHESTER, Ms. MUCARSEL-POWELL, Ms. SCHAKOWSKY, Mr. NEGUSE, Mr. QUIGLEY, Mr. SUOZZI, Mr. RYAN, Mr. RASKIN, Mr. TONKO, Mr. COHEN, Mr. ENGEL, Ms. SEWELL of Alabama, Mr. KENNEDY, Ms. PINGREE, Ms. WASSERMAN SCHULTZ, Mr. LARSEN of Washington, Mr. CUMMINGS, Ms. NORTON, Mr. TED LIEU of California, Ms. CRAIG, Mr. KING of New York, Mrs. LOWEY, Mr. LEWIS, Ms. MCCOLLUM, Mrs. WATSON COLEMAN, Ms. HILL of California, Mr. COX of California, Ms. TLAIB, Ms. SCHRIER, Mr. HASTINGS, Mrs. KIRKPATRICK, Ms. ROYBAL-ALLARD, Mr. KILMER, Ms. STEVENS, Mrs. DINGELL, Ms. KUSTER of New Hampshire, Mr. THOMPSON of Mississippi, Mr. PAPPAS, Mr. DEUTCH, Ms. BROWNLEY of California, Mr. FOSTER, Mr. HECK, Mr. ROUDA, Mrs. NAPOLITANO, Mr. KRISHNAMOORTHI, Mr. POCAN, Mr. DANNY K. DAVIS of Illinois, Mr. LEVIN of California, Mr. CISNEROS, Mrs. DAVIS of California, Ms. MENG, Mr. GOTTHEIMER, Mr. LAWSON of Florida, Ms. JOHNSON of Texas, Ms. PRESSLEY, Ms. BARRAGÁN, Ms. PLASKETT, Mr. CARTWRIGHT, Ms. KELLY of Illinois, Mr. ROSE of New York, Mr. KIM, Mr. PAYNE, Mr. CASE, Mrs. HAYES, Mr. NORCROSS, Mr. LANGEVIN, Ms. MATSUI, Mr. RUIZ, Mr. HUFFMAN, Mrs. DEMINGS, Mr. KILDEE, Ms. HOULAHAN, Mr. DESAULNIER, Mr. BERA, Mrs. LAWRENCE, Mr. TAKANO, Mr. KHANNA, Mr. MCNERNEY, Mr. LUJÁN, Mr. GARCÍA of Illinois, Mr. SOTO, Mr. BLUMENAUER, Ms. JUDY CHU of California, Ms. DEAN, Ms. MOORE, Ms. LOFGREN, Ms. SCANLON, Mr. GRIJALVA, Mr. TRONE, Ms. PORTER, Mr. MALINOWSKI,

Mr. CASTEN of Illinois, Ms. SÁNCHEZ, Mr. EVANS, Mr. CASTRO of Texas, Mr. SWALWELL of California, Mrs. BEATTY, Ms. SPEIER, Ms. BONAMICI, Mr. ESPAILLAT, Mr. SERRANO, Ms. SLOTKIN, Mr. SEAN PATRICK MALONEY of New York, Mr. JEFFRIES, Mrs. MCBATH, Miss RICE of New York, Mr. NADLER, Ms. GARCIA of Texas, Mr. CARSON of Indiana, Ms. WATERS, Mr. GOMEZ, Ms. HAALAND, Mr. THOMPSON of California, Mr. LARSON of Connecticut, Mr. VARGAS, Mr. CICILLINE, Mr. FITZPATRICK, Mr. CLAY, Mr. LEVIN of Michigan, Ms. JACKSON LEE, and Mr. PHILLIPS

FEBRUARY 21, 2020

Reported with an amendment; committed to the Committee of the Whole House on the State of the Union and ordered to be printed

[Strike out all after the enacting clause and insert the part printed in italic]

[For text of introduced bill, see copy of bill as introduced on April 18, 2019]

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 March 15, 2020, 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)). If the Secretary fails to promulgate such final rule by March 15, 2020, then the proposed rule titled "Tobacco Products; Required Warnings for Cigarette Packages and Advertisements" published by the Food and Drug Administration on August 16, 2019 (84 Fed. Reg. 42754) shall be treated as a final rule beginning on March 16, 2020.

(b) CONFORMING CHANGE.—The first section 4(d) of the Federal Cigarette Labeling and Advertising Act (15 U.S.C. 1333(d)) (relating to graphic labeling statements) 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, as applicable, 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, including by updating all references to persons younger than 18 years of age in subpart B of part 1140 of title 21, Code of Federal Regulations.

(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.—

(1) IN GENERAL.—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) 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).

"(D) 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 promulgated the final regulations required by subparagraph (C).".

(2) PRESERVATION OF STATE AND LOCAL AUTHORITY.—Nothing in the amendment made by paragraph (1) shall be construed to affect the preservation of State and local authority pursuant to section 916 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 387p).

(c) PROHIBITING FLAVORING OF TOBACCO PRODUCTS.—

(1) PROHIBITION.—

(A) IN GENERAL.—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 RULES.—

"(i) IN GENERAL.—Beginning on the date that is 1 year after the date of enactment of the Reversing the Youth Tobacco Epidemic Act of 2019, a tobacco product (including its components, parts, and accessories, including the tobacco, filter, or paper) that is not an electronic nicotine delivery system shall not contain, as a con-

stituent (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.

"(ii) RULE OF CONSTRUCTION.—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.

"(iii) APPLICABILITY TO CERTAIN INDIVIDUALS.—Notwithstanding any provision of this Act, no individual who purchases or possess for consumption a tobacco product that is in violation of the prohibition under this subparagraph shall be subject to any criminal penalty under this Act for such purchase or possession, nor shall it be used as a justification to stop, search, or conduct any other investigative measure against any individual.".

(B) 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 paragraph take effect.

(2) FLAVORED ELECTRONIC NICOTINE DELIVERY SYSTEM.—Section 910 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 387j) is amended by inserting at the end the following:

"(h) FLAVORED ELECTRONIC NICOTINE DELIVERY SYSTEMS.—

"(1) RESTRICTION.—Beginning on the date that is 30 days after the date of enactment of the Reversing the Youth Tobacco Epidemic Act of 2019, any flavored electronic nicotine delivery system that is a new tobacco product, including any liquid, solution, or other component or part or its aerosol, shall not contain an artificial or natural flavor (other than tobacco) that is a characterizing flavor, including menthol, mint, strawberry, grape, orange, clove, cinnamon, pineapple, vanilla, coconut, licorice, cocoa, chocolate, cherry, or coffee, unless the Secretary has issued a marketing order as described in paragraph (2). Nothing in this paragraph 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) REVIEW.—The Secretary shall not issue a marketing order under subsection (c)(1)(A)(i) or a substantial equivalence order under subsection (a)(2)(A)(i) for any electronic nicotine delivery system, including any liquid, solution, or other component or part or its aerosol, that contains an artificial or natural flavor (other than tobacco) that is a characterizing flavor, unless the Secretary issues an order finding that the manufacturer has demonstrated that—

"(A) use of the characterizing flavor—

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

"(ii) will not increase the likelihood that individuals who do not use tobacco products, including youth, will start using any tobacco product, including an electronic nicotine delivery system; and

"(B) such electronic nicotine delivery system is not more harmful to users than an elec-

tronic nicotine delivery system that does not contain any characterizing flavors.".

(3) DEFINITION OF ELECTRONIC NICOTINE DELIVERY SYSTEM.—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 (9) through (23), respectively; and

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

"(8) ELECTRONIC NICOTINE DELIVERY SYSTEM.—The term 'electronic nicotine delivery system'—

"(A) means any 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; and

"(B) does not include a product that—

"(i) is approved by the Food and Drug Administration for sale as a tobacco ces-

sation product or for another therapeutic purpose; and

"(ii) is marketed and sold solely for a purpose described in clause (i).".

SEC. 104. PROHIBITION AGAINST REMOTE RETAIL SALES.

(a) IN GENERAL.—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.—

"(A) PROHIBITION.—Not later than 18 months after the date of enactment of the the Reversing the Youth Tobacco Epidemic Act of 2019, the Secretary shall promulgate a final regulation prohibiting the retail sale of all tobacco products other than retail sales through a direct, face-to-face exchange between a retailer and a consumer.

"(B) EXCEPTION FOR CERTAIN CIGAR TOBACCO PRODUCTS.—

"(i) EXCEPTION.—The regulation required by subparagraph (A) shall not apply to tobacco products described in section 910(a)(2)(A)(iii).

"(ii) APPLICABLE REQUIREMENTS.—Not later than 18 months after the date of

enactment of the the Reversing the Youth Tobacco Epidemic Act of 2019, the Secretary shall promulgate regulations regarding the sale and distribution of tobacco products described in section 910(a)(2)(A)(iii) that occur through means other than a direct, face-to-face exchange between a retailer and a consumer in order to prevent the sale and distribution of tobacco products described in section 910(a)(2)(A)(iii) to individuals who have not attained the minimum age established by applicable law for the purchase of such products, including requirements for age verification.

"(C) RELATION TO OTHER AUTHORITY.—Nothing in this paragraph—

"(i) limits the authority of the Secretary to take additional actions under the other paragraphs of this subsection; or

"(ii) preempts the authority of a State or local government to establish restrictions on the retail sale of tobacco products that are at least as restrictive as the prohibition under subparagraph (A).".

(b) APPLICABILITY.—Section 906(d)(4) of the Federal Food, Drug, and Cosmetic Act, as in effect on the day before the date of enactment of this Act, shall continue to apply until the effective date of the regulations required by section 906(d)(4) of such Act, as amended by subsection (a).

SEC. 105. FEES APPLICABLE TO ALL TOBACCO PRODUCTS.

(a) INCREASE IN TOTAL AMOUNT.—Section 919(b)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 387s(b)(1)) is amended by striking subparagraph (K) and inserting the following subparagraphs:

"(K) For fiscal year 2019, $712,000,000.

"(L) For fiscal year 2020, $812,000,000.

"(M) For each subsequent fiscal year, the amount that was applicable for the previous fiscal year, 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.".

(b) APPLICATION OF USER FEES TO ALL CLASSES OF TOBACCO PRODUCT.—

(1) IN GENERAL.—Subparagraph (A) of section 919(b)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 387s(b)(2)) is amended to read as follows:

"(A) IN GENERAL.—

"(i) FISCAL YEARS 2020 AND 2021.—For fiscal years 2020 and 2021, user fees shall be assessed and collected under subsection (a) only with respect to the classes of tobacco products listed in subparagraph (B)(i), and the total such user fees with respect to each such class shall be an amount that is equal to the applicable percentage of each such class for the fiscal year multiplied by the amount specified in paragraph (1) for the fiscal year.

"(ii) SUBSEQUENT FISCAL YEARS.—For fiscal year 2022 and each subsequent fiscal year, user fees shall be assessed and collected under subsection (a) with respect to each class of tobacco products to which this chapter applies (including tobacco products that the Secretary by regulation deems to be subject to this chapter), and the total user fees with respect to each such class shall be—

"(I) with respect to each class of tobacco products listed in subparagraph (B)(i), an amount that is cal-

culated in the same way as the amounts calculated for fiscal years 2020 and 2021 under clause (i), except that for purposes of fiscal years 2022 and subsequent fiscal years, instead of multiplying the applicable percentage of each such class by 'the amount specified in paragraph (1) for the fiscal year', the applicable percentage shall be multiplied by—

"(aa) the amount specified in paragraph (1) for the fiscal year, reduced by

"(bb) the total user fees assessed and collected pursuant to subclause (II) for the fiscal year; and

"(II) with respect to each class of tobacco products to which this chapter applies but which is not listed in subparagraph (B)(i), an amount determined pursuant to a formula under subparagraph (C).".

(2) OTHER TOBACCO PRODUCTS.—Section 919(b)(2) of the Federal Food, Drug, and Cosmetic

Act (21 U.S.C. 387s(b)(2)), as amended by paragraph (1), is further amended by adding at the end the following new subparagraphs:

"(C) ALLOCATION FOR OTHER TOBACCO PRODUCTS.—

"(i) IN GENERAL.—Beginning with fiscal year 2022, the total user fees assessed and collected under subsection (a) each fiscal year with respect to each class of tobacco products not listed in subparagraph (B)(i) shall be an amount that is determined pursuant to a formula developed by the Secretary by regulation using information required to be submitted under subparagraph (D).

"(ii) ALLOCATION FOR OTHER TOBACCO PRODUCTS.—For each class of tobacco products not listed in subparagraph (B)(i), the percentage of fees under the formula under clause (i) for the respective fiscal year shall be equal to the percentage of the gross domestic sales in the previous calendar year that is attributable to such class of tobacco products in such calendar year, as determined by the Secretary.

"(iii) ALLOCATION OF ASSESSMENT WITHIN EACH CLASS OF OTHER TOBACCO PRODUCTS.—The percentage of the total user fee to be paid by each manufacturer or importer of tobacco products in a class not listed in subparagraph (B)(i) shall be determined by the Secretary, based on the percentage of the gross domestics sales of all such classes of tobacco products by all manufacturers and importers in the previous calendar year that is attributable to such manufacturer or importer.

"(iv) EFFECT OF FAILURE TO FINALIZE FORMULA ON TIME.—If the Secretary for any reason fails to finalize by fiscal year 2022 the formula required by this subparagraph for the assessment and collection of user fees for classes of tobacco products not listed in subparagraph (B)(i)—

"(I) the Secretary shall continue to assess and collect fees under subsection (a) with respect to each class of tobacco products listed in subparagraph (B)(i); and

"(II) until the first fiscal year commencing after the finalization of such formula, the exception described in subparagraph (A)(ii)(I) shall not apply.

"(v) REVISIONS BY REGULATION.—Any revisions to the formula promulgated pursuant to this subparagraph shall be by regulation.

"(vi) DEFINITION.—In this subparagraph, the term 'gross domestic sales' means the total value in dollars of the sale or distribution by manufacturers and importers of tobacco products in the United States in classes not listed in subparagraph (B)(i), as determined based on the aggregation of sales data from every manufacturer and importer of tobacco products that submits sales data to the Secretary.

"(D) INFORMATION REQUIRED TO BE SUBMITTED.—Each manufacturer or importer of any tobacco product shall submit to the Secretary the information required under this subparagraph by March 1, 2021, for calendar year 2020, by April 1, 2021, for the period of Janu-

ary 1, 2021, through March 30, 2021, and monthly thereafter. Such information shall include—

"(i) the identification of the manufacturer or importer;

"(ii) the class or classes of tobacco products sold by the manufacturer or importer;

"(iii) the full listing of the finished tobacco products in a class not listed in subparagraph (B)(i) sold or distributed by the manufacturer or importer in the United States; and

"(iv) the gross domestic sales data for each class of finished tobacco products sold or distributed by the manufacturer or importer in the United States.".

(3) PROHIBITED ACT.—Section 301(q)(1)(B) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331(q)(1)(B)) is amended by inserting "919(b)(2)(D)," before "or 920".

(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 subsections (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 paragraph (5);

(2) by redesignating paragraphs (6) and (7) as paragraphs (5) and (6), respectively; and

(3) by amending paragraph (6), as redesignated, to read as follows:

"(6) MEMORANDUM OF UNDERSTANDING.—The Secretary shall request the appropriate Federal agency to enter into a memorandum of understanding that provides for the regular and timely transfer from the head of such agency to the Secretary of all necessary information regarding all tobacco product manufacturers and importers required to pay user fees. The Secretary shall maintain all disclosure restrictions established by the head of such agency regarding the information provided under the memorandum of understanding.".

(e) APPLICABILITY.—The amendments made by subsections (b), (c), and (d) apply beginning with fiscal year

2022. Subject to the amendment made by subsection (a), 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.

(f) REPORT.—For fiscal year 2020 and each subsequent fiscal year for which fees are collected under section 919 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 387s), the Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs, shall, by the end of the respective fiscal year, submit to the Congress financial and performance reports with respect to such fees.

SEC. 106. 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.

SEC. 107. UPDATE TO YOUTH TOBACCO PREVENTION PUBLIC AWARENESS CAMPAIGNS.

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

(1) review all public health awareness campaigns of the Department of Health and Human Services designed to educate at-risk individuals about the harmful effects of tobacco use, including the use of e-cigarettes and other electronic nicotine delivery systems; and

(2) as applicable, modify such campaigns to include awareness and education materials designated for individuals who are 18 to 21 years of age.

(b) CONSULTATION.—In carrying out subsection (a), the Secretary of Health and Human Services may consult with medical and public health associations and nonprofit organizations.

SEC. 108. EXEMPTION FROM PREMARKET APPROVAL OF CERTAIN TOBACCO PRODUCTS.

(a) IN GENERAL.—Section 910(a)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 387j(a)(2)) is amended—

(1) in subparagraph (A)—

(A) in clause (i)(II), by striking "or";

(B) in clause (ii), by striking the period at the end and inserting "; or"; and

(C) by adding at the end the following:

"(iii) subject to subparagraph (C), for the period beginning on the date of the enactment of the Reversing the Youth Tobacco Epidemic Act of 2019 and ending on September 30, 2028, the tobacco product is a cigar and—

"(I) is wrapped in whole tobacco leaf;

"(II) contains a 100-percent leaf tobacco binder;

"(III) contains primarily long filler tobacco;

"(IV) does not have a characterizing flavor other than tobacco;

"(V) weighs more than 6 pounds per 1000 units;

"(VI) has no filter, tip, or non-tobacco mouthpiece;

"(VII)(aa) is made by combining manually the wrapper, filler, and binder and is capped by hand; or

"(bb) has a homogenized tobacco leaf binder and is made in the United States using human hands to lay the 100-percent leaf tobacco binder onto only one machine that bunches, wraps, and caps each individual cigar; and

"(VIII) has a retail price (after discounts or coupons) per cigar of no less than—

"(aa) for calendar years 2019 and 2020, $12; and

"(bb) for each subsequent calendar year, $12 multiplied by any percent increase in the Consumer Price Index for all urban consumers (all items; U.S. city average) since calendar year 2020."; and

(2) by adding at the end the following:

"(C) DETERMINATION OF APPLICABILITY.—

"(i) IN GENERAL.—The Secretary shall, notwithstanding subparagraph (A)(iii) or any determination of substantial equivalence, if any of the conditions specified in clause (ii) are met—

"(I) withdraw any exemption applicable to a tobacco product or products described in such subparagraph;

"(II) require that applications for review under this section be submitted with respect to such product or products; and

"(III) require that manufacturers may only market such tobacco product after the issuance of an order under subsection (c)(1)(A)(i) with respect to such product or products.

"(ii) CONDITIONS.—The conditions specified in this clause are that—

"(I) the Secretary determines that the use of a tobacco product or products described in subparagraph (A)(iii) has resulted in an emerging public health threat;

"(II) data from a National Youth Tobacco Survey (or successor survey) conducted after the date of the enactment of the Reversing the Youth Tobacco Epidemic Act of 2019 identifies a rise in youth usage of tobacco products described in section 910(a)(2)(A)(iii); or

"(III) the Secretary determines that a tobacco product or products no longer meets the criteria specified in such subparagraph.".

(b) NATIONAL ACADEMIES STUDY AND REPORT.—

(1) IN GENERAL.—The Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs, shall enter into an agreement with the National Academies of Sciences, Engineering, and Medicine under which the National Academies shall conduct a study on—

(A) the public health impact of having tobacco products described in subsection (a)(2)(A)(iii) of section 910 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 387j(a)(2)), as amended by subsection (a), exempt from premarket review under such section;

(B) the youth usage of such tobacco products; and

(C) the market share of such products.

(2) REPORT.—The agreement under paragraph (1) shall include a requirement that the National Academies of Sciences, Engineering, and Medicine submit to Congress, not later than December 31, 2026, a report on the findings of the study conducted under such paragraph.

SEC. 109. PUBLIC EDUCATION.

Section 906 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 387f) is amended by adding at the end the following:

"(g) EDUCATION ON TOBACCO PRODUCTS.—

"(1) IN GENERAL.—Not later than 6 months after the date of the enactment of the Reversing the Youth Tobacco Epidemic Act of 2019, the Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs, shall provide educational materials for health care providers, members of the public, and law enforcement officials, regarding—

"(A) the authority of the Food and Drug Administration with respect to the regulation of

tobacco products (including enforcement of such regulation);

"(B) the processes of the Food and Drug Administration for enforcing restrictions on the manufacture and sale of tobacco products;

"(C) the prohibition on characterizing flavors in tobacco products and the under section 907(a)(1) and the exception from such prohibition under subparagraph (C) of such section;

"(D) the public health impact of tobacco products with characterizing flavors; and

"(E) other information as the Secretary determines appropriate.

"(2) CONTENT.—Educational materials provided under paragraph (1) may include—

"(A) explanations of key statutory and regulatory terms, including the terms 'tobacco product,' 'component parts', 'accessories', 'constituent', 'additive', 'tobacco product manufacturer', and 'characterizing flavor';

"(B) an explanation of the Food and Drug Administration's jurisdiction to regulate tobacco products, including tobacco products with characterizing flavors under section 907(a)(1);

"(C) information related to enforcement tools and processes used by the Food and Drug Administration for violations of the prohibition specified in section 907(a)(1);

"(D) an explanation of the health effects of using tobacco products, including those with characterizing flavors; and

"(E) information on resources available related to smoking cessation.

"(3) FORMAT.—Educational materials provided under paragraph (1) may be—

"(A) published in any format, including an Internet website, video, fact sheet, infographic, webinar, or other format, as the Secretary determines is appropriate and applicable; and

"(B) tailored for the unique needs of health care providers, members of the public, law enforcement officers, and other audiences, as the Secretary determines appropriate.".

SEC. 110. REGULATIONS FOR RECORDKEEPING CONCERNING TRACKING AND TRACING.

The Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs, shall promulgate the regulations required by section 920(b) of the

Federal Food, Drug, and Cosmetic Act (21 U.S.C. 387t) in accordance with the following schedule:

(1) Not later than 1 year after the date of enactment of this Act, the Secretary shall issue proposed regulations.

(2) Not later than 2 years after the date of enactment of this Act, the Secretary shall promulgate final regulations.

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 a tobacco product that—

(A) is not a cigarette; and

(B) is a roll of tobacco wrapped in leaf tobacco or any substance containing tobacco.

(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.—The term "electronic nicotine delivery system"—

(A) means any 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; and

(B) does not include a product that—

(i) is approved by the Food and Drug Administration for sale as a tobacco cessation product or for another therapeutic purpose; and

(ii) is marketed and sold solely for a purpose described in clause (i).

(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).

TITLE III—PUBLIC HEALTH PROGRAMS

SEC. 301. OUTREACH TO MEDICALLY UNDERSERVED COMMUNITIES.

The Secretary shall ensure that programs at the Centers for Disease Control and Prevention related to outreach to medically underserved communities, including racial and ethnic minority populations, include efforts to educate and provide guidance regarding effective evidence-based strategies—

(1) to prevent tobacco, e-cigarette, and nicotine addiction; and

(2) for smoking cessation and the cessation of the use of e-cigarettes and electronic nicotine delivery systems.

SEC. 302. DEMONSTRATION GRANT PROGRAM TO DEVELOP STRATEGIES FOR SMOKING CESSATION IN MEDICALLY UNDERSERVED COMMUNITIES.

(a) IN GENERAL.—The Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall establish a demonstration program to award grants to or contract with State, local, Tribal, or territorial public health departments to support—

(1) the development of improved evidence-based strategies for smoking cessation and the cessation of the use of e-cigarettes and electronic nicotine delivery systems for populations in medically underserved communities, particularly racial and ethnic minority populations;

(2) the development of improved communication and outreach tools to reach populations in medically underserved communities, particularly racial and ethnic minority populations, addicted to tobacco and e-cigarette products; and

(3) improved coordination, access, and referrals to services for smoking cessation and the cessation of the use of e-cigarettes and electronic nicotine delivery systems, including smoking cessation products and mental health and counseling services.

(b) APPLICATION.—To be eligible to receive a grant under subsection (a), a State, local, Tribal, or territorial public health department shall submit to the Secretary an application at such time, in such manner, and containing such information as the Secretary may require.

(c) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this section, $3,000,000 for each of fiscal years 2020 through 2024.

TITLE IV—NICOTINE OR VAPING ACCESS PROTECTION AND ENFORCEMENT

SECTION 401. SHORT TITLE.

This title may be cited as the "Nicotine or Vaping Access Protection and Enforcement Act of 2019" or the "NO VAPE Act of 2019".

SEC. 402. INCREASING CIVIL PENALTIES APPLICABLE TO CERTAIN VIOLATIONS OF RESTRICTIONS ON SALE AND DISTRIBUTION OF TOBACCO PRODUCTS.

(a) PENALTIES.—Subparagraph (A) of section 103(q)(2) of the Family Smoking Prevention and Tobacco Control Act (21 U.S.C. 333 note) is amended to read as follows:

"(A) IN GENERAL.—The amount of the civil penalty to be applied for violations of restrictions promulgated under section 906(d), as described in paragraph (1), shall be as follows:

"(i) With respect to a retailer with an approved training program, the amount of the civil penalty shall not exceed—

"(I) in the case of the first violation, $0, together with the issuance of a warning letter to the retailer;

"(II) in the case of a second violation within a 12-month period, $500;

"(III) in the case of a third violation within a 24-month period, $1,000;

"(IV) in the case of a fourth violation within a 24-month period, $4,000;

"(V) in the case of a fifth violation within a 36-month period, $10,000; and

"(VI) in the case of a sixth or subsequent violation within a 48-month period, $20,000 as determined by the Secretary on a case-by-case basis.

"(ii) With respect to a retailer that does not have an approved training program, the amount of the civil penalty shall not exceed—

"(I) in the case of the first violation, $500;

"(II) in the case of a second violation within a 12-month period, $1,000;

"(III) in the case of a third violation within a 24-month period, $2,000;

"(IV) in the case of a fourth violation within a 24-month period, $4,000;

"(V) in the case of a fifth violation within a 36-month period, $10,000; and

"(VI) in the case of a sixth or subsequent violation within a 48-month period, $20,000 as determined by the Secretary on a case-by-case basis.".

(b) APPLICABILITY.—The amendment made by subsection (a) applies with respect to a violation of a restriction promulgated under section 906(d)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 387f(d)(1)), as described in section 103(q)(1) of the Family Smoking Prevention and Tobacco Control Act (21 U.S.C. 333 note), occurring on or after the date that is 6 months after the enactment of this Act. The penalties specified in such section 103(q)(1), as in effect on the day before such date, shall continue to apply to violations occurring before such date.

SEC. 403. STUDY AND REPORT ON E-CIGARETTES.

Not later than 5 years after the date of enactment of this Act, the Comptroller General of the United States shall—

(1) complete a study on—

(A) the relationship of e-cigarettes to tobacco cessation;

(B) the perception of the harmful effects of e-cigarettes; and

(C) the effects of secondhand exposure to smoke from e-cigarettes; and

(2) submit to the Congress a report on the results of such study, including recommendations based on such results.

Union Calendar No. 324

116TH CONGRESS
2D SESSION

H. R. 2339

[Report No. 116–402]

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.

FEBRUARY 21, 2020

Reported with an amendment; committed to the Committee of the Whole House on the State of the Union and ordered to be printed