116TH CONGRESS
2D SESSION

H. R. 2339

AN ACT

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 ''Protecting American Lungs and Reversing the Youth Tobacco Epidemic Act of 2020''.

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, 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.

(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 con-

strued 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) 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 Protecting American Lungs and Reversing the Youth Tobacco Epidemic Act of 2020, 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 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, mango, 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 for individual consumption, possesses for individual consumption, or consumes, a tobacco product that is in violation of the prohibition under this subparagraph, including a tobacco product that

contains a characterizing flavor of menthol, shall be subject to any criminal penalty under this Act for such purchase, possession, or consumption, nor shall such purchase, possession, or consumption 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 amendment made to such section 907(a)(1) by this paragraph takes 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 Protecting American Lungs and Reversing the Youth Tobacco Epidemic Act of 2020, any flavored

electronic nicotine delivery system that is a new tobacco product, including any solution or other component or part (such as a liquid or its aerosol) shall not contain an artificial or natural flavor (other than tobacco) that is a characterizing flavor, including menthol, mint, mango, 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 electronic 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' 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.''.

(4) LIMITATION ON ENFORCEMENT.—A law enforcement officer of a State or political subdivision thereof may not enforce (including by making any stop, search, seizure, or arrest or by pursuing any prosecution, trial, or punishment) any provision of section 907(a)(1)(A) or 910(h) of the Federal Food, Drug, and Cosmetic Act, as amended and added by this subsection.

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 Protecting American Lungs and Reversing the Youth Tobacco Epidemic Act of 2020, the Secretary shall promulgate a final regulation pro-

hibiting 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 Protecting American Lungs and Reversing the Youth Tobacco Epidemic Act of 2020, 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 other provisions of this Act; or

''(ii) preempts the authority of a State or local government to establish restrictions on the retail sale of tobacco products that are in addition to, or more stringent than, 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 years 2019 and 2020, $712,000,000.

"(L) For fiscal year 2021, $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) APPLICABILITY.—

(1) FISCAL YEARS 2020 AND 2021.—Except as amended by subsection (a), for fiscal years 2020 and 2021, section 919 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 387s) shall apply as in effect on the day before the date of enactment of this Act.

(2) SUBSEQUENT FISCAL YEARS.—The amendments made by subsections (c) through (f) apply beginning with fiscal year 2022.

(c) ALLOCATIONS OF ASSESSMENT BY CLASS OF TOBACCO PRODUCTS.—Paragraph (2) of section 919(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 387s(b)) is amended to read as follows:

''(2) ALLOCATIONS OF ASSESSMENT BY CLASS OF TOBACCO PRODUCTS.—

''(A) IN GENERAL.—The total user fees assessed and collected under subsection (a) each fiscal year (beginning with fiscal year 2022) with respect to each class of tobacco products to which this chapter applies shall be an amount that is equal to the applicable percentage of each class for the fiscal year multiplied by the amount specified in paragraph (1) for the fiscal year.

''(B) APPLICABLE PERCENTAGE.—

''(i) IN GENERAL.—For purposes of subparagraph (A), the applicable percentage for a fiscal year for each class of tobacco product shall be the percentage determined by dividing—

''(I) the product of the gross domestic volume of the class multiplied by the tax rate applicable to the class under section 5701 of the Internal Revenue Code of 1986; and

''(II) the sum of the products determined under subclause (I) for all classes of tobacco products.

''(ii) DEFINITION.—For purposes of clause (i), the term 'gross domestic volume' means the volume of tobacco products—

''(I) removed (as defined by section 5702 of the Internal Revenue Code of 1986); and

''(II) not exempt from tax under chapter 52 of the Internal Revenue Code of 1986 at the time of their removal under that chapter or the Harmonized Tariff Schedule of the United States (19 U.S.C. 1202).''.

(d) 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 allocated on a pro rata basis among the manufacturers and importers of each class of tobacco products to which this chapter applies based on the percentage share of each manufacturer's or importer's share of gross domestic volume within such class on a quarterly basis, based on data for the second preceding quarter''.

(e) OTHER 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; REPORTING.—

''(A) TRANSFER OF INFORMATION.—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.

''(B) REPORTING.—

''(i) MANUFACTURER REPORTING.—The Secretary may require the manufac-

turers and importers of each class of tobacco products to which this chapter applies to submit such information, by such time, and in such manner, as the Secretary determines to be necessary to implement this section.

''(ii) REPORTS TO CONGRESS.—For fiscal year 2020 and each subsequent fiscal year for which fees are collected under this section, the Secretary shall, not later than 120 days after the end of the respective fiscal year, submit to the Congress financial and performance reports with respect to such fees.''.

(f) 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)(6)(B),'' before ''or 920''.

SEC. 106. REGULATION OF PRODUCTS CONTAINING ALTERNATIVE 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 pro-

viding for the regulation of products containing alternative 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) ALTERNATIVE NICOTINE.—In this section, the term ''alternative nicotine'' means nicotine that is not made or derived from tobacco plants and may include nicotine that is chemically synthesized, synthesized from recombinant genetic technology, or extracted from non-tobacco plants.

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

(a) IN GENERAL.—The Secretary of Health and Human Services 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 designed 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 REVIEW 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 Protecting American Lungs and Reversing the Youth Tobacco Epidemic Act of 2020 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 Protecting American Lungs and Reversing the Youth Tobacco Epidemic Act of 2020 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, Engineer-

ing, 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), 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.—Beginning not later than 6 months after the date of the enactment of the Protecting American Lungs and Reversing the Youth

Tobacco Epidemic Act of 2020, the Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs and in consultation with the Surgeon General of the Public Health Service, 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 general processes of the Food and Drug Administration for enforcing restrictions on the manufacture and sale of tobacco products;

"(C) the general enforcement actions the Food and Drug Administration may take to implement the prohibition on characterizing flavors in tobacco products under section 907(a)(1);

"(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) general educational 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) information on the health effects of using tobacco products, including those with the characterizing flavors referred to in section 907(a)(1); 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.

''(4) FUNDING.—To carry out this subsection, there is authorized to be appropriated, and there is appropriated, out of any funds in the Treasury not otherwise appropriated, $5,000,000 for each of fiscal years 2021 through 2025. Funds made available by the preceding sentence to carry out this subsection shall be in addition to funds that are derived from fees under section 919 and are otherwise made available to carry out this chapter.''.

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'' 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.

(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.

Section 399V of the Public Health Service Act (42 U.S.C. 280g–11) is amended—

(1) in subsection (b)—

(A) by redesignating paragraphs (4) and (5) as paragraphs (5) and (6), respectively; and

(B) by inserting after paragraph (3) the following:

''(4) to educate and provide guidance to medically underserved communities, particularly racial and ethnic minority populations, regarding effective evidence-based strategies—

''(A) to prevent tobacco, e-cigarette, and nicotine addiction, including among youth; and

''(B) for smoking cessation, including cessation of the use of menthol-flavored tobacco products, and the cessation of the use of e-cigarettes and electronic nicotine delivery systems;'';

(2) in subsection (d)(1)(B), by inserting '', including chronic diseases related to and caused by tobacco use'' after ''diseases''; and

(3) in subsection (j), by striking ''are authorized to be appropriated, such sums as may be necessary to carry out this section for each of fiscal years 2010 through 2014'' and inserting ''is authorized to be appropriated, and there is appropriated, out of any funds in the Treasury not otherwise appropriated, $75,000,000 to carry out this section for each of fiscal years 2021 through 2025''.

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

Part B of title III of the Public Health Service Act (42 U.S.C. 243 et seq.) is amended by inserting after section 317U (42 U.S.C. 247b–23) the following:

''SEC. 317V. 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, or Tribal public health departments to support—

''(1) the development of improved evidence-based strategies for smoking cessation, including

cessation of the use of menthol-flavored tobacco products, 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 products, including e-cigarettes and menthol-flavored tobacco products; and

''(3) improved coordination, access, and referrals to services for tobacco cessation and the cessation of the use of e-cigarettes and electronic nicotine delivery systems, including tobacco cessation products approved by the Food and Drug Administration and mental health and counseling services.

''(b) APPLICATION.—To be eligible to receive a grant under subsection (a), a State, local, or Tribal 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.—To carry out this section, there is authorized to be appropriated, and there is appropriated, out of any funds in

the Treasury not otherwise appropriated, $75,000,000 for each of fiscal years 2021 through 2025.''.

SEC. 303. PUBLIC AWARENESS, EDUCATION, AND PREVENTION CAMPAIGN.

Part B of title III of the Public Health Service Act (42 U.S.C. 243 et seq.), as amended by section 302, is further amended by inserting after section 317V the following new section:

''SEC. 317W. PUBLIC AWARENESS, EDUCATION, AND PREVENTION CAMPAIGN REGARDING TOBACCO.

''(a) IN GENERAL.—The Secretary, acting through the Director of the Centers for Disease Control and Prevention and in consultation with the Surgeon General of the Public Health Service, shall develop and implement a national campaign to educate youth and young adults, parents, clinicians, health professionals, and others about the harms associated with the use by youth and young adults of tobacco products, including e-cigarettes.

''(b) REQUIREMENTS.—The campaign under this section shall—

''(1) be an evidence-based media and public engagement initiative;

''(2) be carried out through competitively bid contracts;

''(3) include the development of culturally and linguistically competent resources that may be tailored for communities with high rates of youth tobacco use;

''(4) be complementary to, and coordinated with, any other Federal efforts; and

''(5) include message testing to identify culturally and linguistically competent and effective messages for behavioral change.

''(c) OPTIONAL COMPONENTS.—The campaign under this section may include—

''(1) the use of—

''(A) television, radio, print, the internet, and other commercial marketing venues; and

''(B) in-person public communications; and

''(2) the award of grants to State, local, and Tribal public health departments to encourage partnerships with community organizations and health care providers to develop and deliver evidence-based strategies to prevent youth tobacco use.

''(d) FUNDING.—To carry out this section, there is authorized to be appropriated, and there is appropriated, out of any funds in the Treasury not otherwise appropriated, $45,000,000 for each of fiscal years 2021 through 2025.''.

SEC. 304. TOBACCO CESSATION TREATMENT GRANTS TO HEALTH CENTERS.

(a) IN GENERAL.—Section 330 of the Public Health Service Act (42 U.S.C. 254b) is amended—

(1) by redesignating subsections (k) through (r) as subsections (l) through (s), respectively; and

(2) by adding after subsection (j) the following new subsection:

''(k) TOBACCO CESSATION GRANTS.—

''(1) IN GENERAL.—The Secretary may award grants to health centers to provide comprehensive tobacco cessation treatment, including counseling and tobacco cessation therapies.

''(2) FUNDING.—For the purpose of carrying out this subsection, in addition to other amounts available for such purpose, there is authorized to be appropriated, and there is appropriated, out of funds in the Treasury not otherwise appropriated, $125,000,000 for each of fiscal years 2021 through 2025.''.

(b) CONFORMING CHANGES.—Section 330 of the Public Health Service Act (42 U.S.C. 254b) is amended—

(1) in subsection (c)(3)(B), by striking ''(k)(3)(J)'' and inserting ''(l)(3)(J)'';

(2) in subsection (e)(1)(B), by striking ''(k)(3)'' each place it appears and inserting ''(l)(3)'';

(3) in subsection (l)(3)(H), as redesignated, by striking ''or (p)'' and inserting ''or (q)'';

(4) in subsection (m), as redesignated—

(A) by striking ''(k)(3)'' and inserting ''(l)(3)''; and

(B) by striking ''(m)'' and inserting ''(n)'';

(5) in subsection (q), as redesignated, by striking ''(k)(3)(G)'' and inserting ''(l)(3)(G)'';

(6) in subsection (s)(2)(A), as redesignated—

(A) by striking ''(k)(3)'' and inserting ''(l)(3)''; and

(B) by striking ''(k)(3)(H)'' and inserting ''(l)(3)(H)''; and

(7) in subsection (s)(3)(I), as redesignated, by striking ''(q)(4)'' and inserting ''(r)(4)''.

(c) TECHNICAL CORRECTIONS.—

(1) Section 330(h)(5)(B) of the Public Health Service Act (42 U.S.C. 254b(h)(5)(B)) is amended by striking ''substance abuse'' each place it appears and inserting ''substance use disorder''.

(2) Subclause (II) of subsection (l)(3)(E)(i), as redesignated, of section 330 of the Public Health Service Act (42 U.S.C. 254b) is amended by moving the indentation 2 ems to the left.

SEC. 305. GRANTS FOR RESEARCH.

Part P of title III of the Public Health Service Act (42 U.S.C. 280g et seq.) is amended by adding at the end the following new section:

"SEC. 399V–7. GRANTS FOR RESEARCH ON PREVENTION, AND CESSATION, OF THE USE OF TOBACCO PRODUCTS.

''(a) IN GENERAL.—The Secretary shall award grants to support—

''(1) research to develop and improve effective strategies for prevention, and cessation, of the use of tobacco products, including—

''(A) cessation of the use of flavored combustible cigarettes, including menthol-flavored cigarettes;

''(B) cessation of the use of e-cigarette products; and

''(C) prevention and cessation strategies targeted toward youth; and

''(2) research to aid in the development of safe and effective tobacco cessation therapies, including therapies appropriate for populations under the age of 18.

''(b) FUNDING.—To carry out this section, there is authorized to be appropriated, and there is appropriated, out of any funds in the Treasury not otherwise appro-

priated, $75,000,000 for each of fiscal years 2021 through 2025.''.

TITLE IV—NICOTINE OR VAPING ACCESS PROTECTION AND ENFORCEMENT

SEC. 401. 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 day that is 6 months after the date of enactment of this Act. The penalties specified in

section 103(q)(2)(A) of the Family Smoking Prevention and Tobacco Control Act (21 U.S.C. 333 note), as in effect on the day before the date of enactment of this Act, shall continue to apply to violations occurring before the day specified in the preceding sentence.

SEC. 402. 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.

TITLE V—EXCISE TAX ON NICOTINE USED IN VAPING, ETC.

SEC. 501. IMPOSITION OF TAX ON NICOTINE FOR USE IN VAPING, ETC.

(a) IN GENERAL.—Section 5701 of the Internal Revenue Code of 1986 is amended by redesignating subsection

(h) as subsection (i) and by inserting after subsection (g) the following new subsection:

''(h) NICOTINE.—On taxable nicotine, manufactured in or imported into the United States, there shall be imposed a tax equal to the dollar amount specified in section 5701(b)(1) (or, if greater, $50.33) per 1,810 milligrams of nicotine (and a proportionate tax at the like rate on any fractional part thereof).''.

(b) TAXABLE NICOTINE.—Section 5702 of such Code is amended by adding at the end the following new subsection:

''(q) TAXABLE NICOTINE.—

''(1) IN GENERAL.—Except as otherwise provided in this subsection, the term 'taxable nicotine' means any nicotine which has been extracted, concentrated, or synthesized.

''(2) EXCEPTION FOR PRODUCTS APPROVED BY FOOD AND DRUG ADMINISTRATION.—Such term shall not include any nicotine if the manufacturer or importer thereof demonstrates to the satisfaction of the Secretary of Health and Human Services that such nicotine will be used in—

''(A) a drug—

''(i) that is approved under section 505 of the Federal Food, Drug, and Cos-

metic Act or licensed under section 351 of the Public Health Service Act; or

''(ii) for which an investigational use exemption has been authorized under section 505(i) of the Federal Food, Drug, and Cosmetic Act or under section 351(a) of the Public Health Service Act; or

''(B) a combination product (as described in section 503(g) of the Federal Food, Drug, and Cosmetic Act), the constituent parts of which were approved or cleared under section 505, 510(k), or 515 of such Act.

''(3) COORDINATION WITH TAXATION OF OTHER TOBACCO PRODUCTS.—Cigars, cigarettes, smokeless tobacco, pipe tobacco, and roll-your-own tobacco shall not be treated as containing taxable nicotine solely because the nicotine naturally occurring in the tobacco from which such product is manufactured has been concentrated during the ordinary course of manufacturing.''.

(c) TAXABLE NICOTINE TREATED AS A TOBACCO PRODUCT.—Section 5702(c) of such Code is amended by striking ''and roll-your-own tobacco'' and inserting ''roll-your-own tobacco, and taxable nicotine''.

(d) MANUFACTURER OF TAXABLE NICOTINE.—Section 5702 of such Code, as amended by subsection (b), is further amended by adding at the end the following new subsection:

''(r) MANUFACTURER OF TAXABLE NICOTINE.—

''(1) IN GENERAL.—Any person who extracts, concentrates, or synthesizes nicotine shall be treated as a manufacturer of taxable nicotine (and as manufacturing such taxable nicotine).

''(2) APPLICATION OF RULES RELATED TO MANUFACTURERS OF TOBACCO PRODUCTS.—Any reference to a manufacturer of tobacco products, or to manufacturing tobacco products, shall be treated as including a reference to a manufacturer of taxable nicotine, or to manufacturing taxable nicotine, respectively.''.

(e) EFFECTIVE DATE.—

(1) IN GENERAL.—The amendments made by this section shall apply to articles manufactured or imported in calendar quarters beginning more than 90 days after the date of the enactment of this Act.

(2) TRANSITION RULE FOR PERMIT AND BOND REQUIREMENTS.—A person which is lawfully engaged in business as a manufacturer or importer of taxable nicotine (within the meaning of subchapter

A of chapter 52 of the Internal Revenue Code of 1986, as amended by this section) on the date of the enactment of this Act, first becomes subject to the requirements of subchapter B of chapter 52 of such Code by reason of the amendments made by this section, and submits an application under such subchapter B to engage in such business not later than 90 days after the date of the enactment of this Act, shall not be denied the right to carry on such business by reason of such requirements before final action on such application.

TITLE VI—FURTHER HEALTH INVESTMENTS

SEC. 601. WAIVING MEDICARE COINSURANCE FOR COLORECTAL CANCER SCREENING TESTS.

Section 1833(a) of the Social Security Act (42 U.S.C. 1395l(a)) is amended—

(1) in the second sentence, by striking ''section 1834(0)'' and inserting ''section 1834(o)'';

(2) by moving such second sentence 2 ems to the left; and

(3) by inserting the following third sentence following such second sentence: ''For services furnished on or after January 1, 2024, paragraph (1)(Y) shall apply with respect to a colorectal cancer screening

test regardless of the code that is billed for the establishment of a diagnosis as a result of the test, or for the removal of tissue or other matter or other procedure that is furnished in connection with, as a result of, and in the same clinical encounter as the screening test.''.

SEC. 602. SAFE HARBOR FOR HIGH DEDUCTIBLE HEALTH PLANS WITHOUT DEDUCTIBLE FOR CERTAIN INHALERS.

(a) IN GENERAL.—Section 223(c)(2)(C) of the Internal Revenue Code of 1986 is amended—

(1) by striking ''for preventive care'' and inserting ''for one or more of the following:

''(i) Preventive care'', and

(2) by adding at the end the following new clause:

''(ii) Inhalers or nebulizers for treatment of any chronic lung disease (and any medicine or drug which is delivered through such inhaler or nebulizer for treatment of such disease).''.

(b) CONFORMING AMENDMENT.—The heading for section 223(c)(2)(C) of such Code is amended by striking ''PREVENTIVE CARE DEDUCTIBLE'' and inserting ''CERTAIN DEDUCTIBLES''.

(c) EFFECTIVE DATE.—The amendments made by this section shall apply to months beginning after the date of the enactment of this Act.

Passed the House of Representatives February 28, 2020.

Attest:

Clerk.

116TH CONGRESS
2D SESSION

H. R. 2339

AN ACT

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