AMENDMENT IN THE NATURE OF A SUBSTITUTE

TO H.R. 2339

OFFERED BY M__. _____

Strike all after the enacting clause and insert the following:

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

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

(a) IN GENERAL.—Not later than 1 year after the date of enactment of this Act, the Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs, shall promulgate a final rule amending part 1140 of subchapter K of title 21, Code of Federal Regulations—

(1) to apply the provisions of such part 1140 to all tobacco products, 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) PROHIBITION AGAINST REMOTE RETAIL SALES.—Paragraph (4) of section 906(d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 387f(d)) is amended to read as follows:

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

(d) PROHIBITING FLAVORING OF TOBACCO PRODUCTS.—

(1) PROHIBITION.—

(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 constituent (including a smoke constituent) or additive, an artificial or natural flavor (other than tobacco) that is a characterizing flavor of the tobacco product or tobacco smoke or an herb or spice, including menthol, mint, strawberry, grape, orange, clove, cinnamon, pineapple, vanilla, coconut, licorice, cocoa, chocolate, cherry, or coffee.

"(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 sec-

tions 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.''.

(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 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'—

''(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).''.

SEC. 104. 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 PRODUCTS.—Paragraph (2) of section 919(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 387s(b)(2)) is amended to read as follows:

''(2) ALLOCATIONS OF ASSESSMENT BY CLASS OF TOBACCO PRODUCTS.—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 shall be an amount that is determined pursuant to a formula developed by the Secretary.''.

(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 (7) and (8), respectively; and

(3) by amending paragraph (7) to read as follows:

''(7) 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.

SEC. 105. REGULATION OF PRODUCTS CONTAINING SYNTHETIC NICOTINE.

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

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

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

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

SEC. 106. 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.

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 gen-

eral 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).

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