

REVERSING THE YOUTH TOBACCO EPIDEMIC ACT OF 2019

FEBRUARY 21, 2020.—Committed to the Committee of the Whole House on the State
of the Union and ordered to be printed

Mr. PALLONE, from the Committee on Energy and Commerce,
submitted the following

R E P O R T

together with

DISSENTING VIEWS

[To accompany H.R. 2339]

The Committee on Energy and Commerce, to whom was referred the bill (H.R. 2339) to amend the Federal Food, Drug, and Cosmetic Act with respect to the sale and marketing of tobacco products, and for other purposes, having considered the same, reports favorably thereon with an amendment and recommends that the bill as amended do pass.

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The amendment is as follows:
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:

Sec. 1. Short title.
Sec. 2. Table of contents.

TITLE I—FOOD AND DRUG ADMINISTRATION

Sec. 101. Cigarette graphic health warnings.
Sec. 102. Advertising and sales parity for all deemed tobacco products.
Sec. 103. Reducing child and adolescent nicotine addiction.
Sec. 104. Prohibition against remote retail sales.
Sec. 105. Fees applicable to all tobacco products.
Sec. 106. Regulation of products containing synthetic nicotine.
Sec. 107. Update to youth tobacco prevention public awareness campaigns.
Sec. 108. Exemption from premarket approval of certain tobacco products.
Sec. 109. Public education.
Sec. 110. Regulations for recordkeeping concerning tracking and tracing.

TITLE II—FEDERAL TRADE COMMISSION

Sec. 201. Advertising of tobacco products.

TITLE III—PUBLIC HEALTH PROGRAMS

Sec. 301. Outreach to medically underserved communities.
Sec. 302. Demonstration grant program to develop strategies for smoking cessation in medically underserved communities.

TITLE IV—NICOTINE OR VAPING ACCESS PROTECTION AND ENFORCEMENT

Sec. 401. Short title.
Sec. 402. Increasing civil penalties applicable to certain violations of restrictions on sale and distribution of tobacco products.
Sec. 403. Study and report on e-cigarettes.

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 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 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 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. 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 dis-

tribution 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 calculated 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 domestic 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 January 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 ef-

fect 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 non-profit 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 pre-market 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.

I. PURPOSE AND SUMMARY

H.R. 2339, the “Reversing the Youth Tobacco Epidemic Act of 2019”, was introduced on April 18, 2019, by House Committee on Energy and Commerce Chairman Frank Pallone, Jr. (D-NJ) and referred to the Committee on Energy and Commerce. H.R. 2339 amends the Federal Food, Drug, and Cosmetic Act (FFDCA) to strengthen the authority of the Food and Drug Administration (FDA) over tobacco products and provide a comprehensive approach to address the youth tobacco epidemic, which has surged in recent years with the introduction of electronic nicotine delivery system (ENDS) products, such as electronic cigarettes (e-cigarettes).

The legislation prohibits the manufacture and sale of all flavored tobacco products and requires the removal of all flavored ENDS products from the market within 30 days, makes it unlawful to market, advertise, or promote ENDS products to individuals under the age of 21, and directs the FDA to prohibit non-face-to-face sales of certain tobacco products. Additionally, H.R. 2339 provides FDA with the authority to collect user fees from all classes of tobacco products, including ENDS products, and increases the annual user fees collected for tobacco products. The bill also requires the Federal Trade Commission (FTC) to issue an annual report to Congress on the domestic sales, advertising, and promotional activities

of cigarette, cigar, smokeless tobacco, and ENDS manufacturers, in addition to other provisions.

H.R. 2339 takes the necessary steps to prevent the loss of an entirely new generation to a lifetime of nicotine addiction by enhancing FDA’s regulatory authority to restrict the marketing and sale of tobacco products that appeal to young people and reverse the epidemic levels of youth tobacco usage.

II. BACKGROUND AND NEED FOR LEGISLATION

Tobacco use remains the leading cause of preventable death, disability, and disease in the United States.¹ Each year, nearly half a million Americans die prematurely from smoking or exposure to secondhand smoke, and another 16 million Americans live with a serious illness caused by smoking.² Despite this, the Centers for Disease Control and Prevention (CDC) estimates that more than 49 million adults in the United States continue to use tobacco products, including combustible cigarettes, cigars, e-cigarettes, and smokeless tobacco, among others.³ Even more concerning, in 2019, about 6.2 million U.S. middle and high school students were current (past 30 day) users of some type of tobacco product.⁴

According to results from the National Youth Tobacco Survey (NYTS), an annual survey conducted in collaboration by CDC and FDA that tracks youth usage of tobacco products, for the last six years, e-cigarettes have been the most commonly used tobacco product among middle and high school students.⁵ Based on this data, in 2019, more than one out of every four high school students are current users of e-cigarettes.⁶ During the 2017–2018 period alone, current e-cigarette use by high schoolers increased by 78 percent.⁷ CDC attributed this significant rise in youth usage of e-cigarettes to the “recent popularity of e-cigarettes shaped like a USB flash drive, such as JUUL; these products can be used discreetly, have a high nicotine content, and come in flavors that appeal to youths.”⁸

The widespread availability and appeal of kid-friendly flavors has significantly contributed to the rapid rise in e-cigarette use by young people, with the availability of flavors such as mint, candy, fruit, and chocolate being one of the driving reasons why students report using e-cigarettes.⁹ Several findings have also shown that youth users also perceive flavored tobacco products to be less harm-

¹Centers for Disease Control and Prevention, *Smoking & Tobacco Use*, Data and Statistics (www.cdc.gov/tobacco/data_statistics/index.htm).

²*Id.*

³Centers for Disease Control and Prevention, *Tobacco Product Use and Cessation Indicators Among Adults—United States, 2018* (www.cdc.gov/mmwr/volumes/68/wr/mm6845a2.htm?s_cid=mm6845a2_w).

⁴Centers for Disease Control and Prevention, *6.2 Million middle and high school students used tobacco products in 2019* (www.cdc.gov/media/releases/2019/1205-nyts-2019.html).

⁵*Id.*

⁶*Id.*

⁷Centers for Disease Control and Prevention, *Notes from the Field: Use of Electronic Cigarettes and Any Tobacco Product Among Middle and High School Students—United States, 2011–2018*, Morbidity and Mortality Weekly Report (MMWR) (Nov. 16, 2018) (www.cdc.gov/mmwr/volumes/67/wr/mm6745a5.htm).

⁸*Id.*

⁹Food and Drug Administration, *Youth Tobacco Use: Results from the National Youth Tobacco Survey* (www.fda.gov/tobacco-products/youth-and-tobacco/youth-tobacco-use-results-national-youth-tobacco-survey).

ful than non-flavored alternatives.¹⁰ Additionally, data from the Population Assessment of Tobacco and Health (PATH) Study found that 79 percent of youth (age 12 to 17) and 89 percent of young adults (age 18 to 24) stated that they used a tobacco product because the product “comes in flavors that I like.”¹¹ Evidence has also demonstrated that menthol flavored cigarettes contribute to increased smoking initiation among young people, as well as greater likelihood of addiction.¹²

In November 2018, FDA acknowledged that the sharp rise in e-cigarette use by young people represented an epidemic and resulted in an overall uptick in youth tobacco product use after several years of decline. These statistics are concerning because the use of e-cigarettes, particularly ENDS products that contain high levels of nicotine, place young people at significant risk for developing nicotine addiction. Nicotine exposure harms brain development during adolescence and studies have shown that youth who use e-cigarettes are more likely to start smoking combustible cigarettes as well.¹³

Legislation is needed to address the underlying causes of this significant rise in youth usage, including the availability of flavored e-cigarette and other tobacco products, as well as kid-appealing marketing and promotional tactics that may influence tobacco use among youth.

TITLE I—FOOD AND DRUG ADMINISTRATION

Title I of H.R. 2339 will reduce child and adolescent nicotine addiction and bring regulatory parity to the treatment of all tobacco products under FDA’s authorities. In order to reduce the appeal of tobacco products to kids and eliminate the kid-friendly flavors that attract young people to initiate use, title I prohibits all characterizing flavors in all tobacco products, including menthol, and requires the removal of all flavored e-cigarettes from the market within 30 days following the enactment of the legislation. Title I also prohibits most remote retail sales for tobacco products and directs FDA to issue final regulations that require face-to-face sales for most tobacco products given the lack of sufficient age verification mechanisms that adequately safeguard against underage tobacco sales online today.

This title also extends FDA user fees to all classes of tobacco products, including ENDS, and increases the total amount of fees collected annually by \$100 million. Under current law, FDA does not have the authority to assess user fees from ENDS manufactur-

¹⁰ Huang, L.-L., et al., “Impact of Non-menthol Flavours in Tobacco Products on Perceptions and Use Among Youth, Young Adults and Adults: A Systematic Review,” *Tobacco Control*, 26(6):709–719, 2017. Kowitz, S.D., et al., “Perceptions and Experiences With Flavored Non-Menthol Tobacco Products: A Systematic Review of Qualitative Studies,” *International Journal of Environmental Research and Public Health*, 14(4):338, 2017. Pepper, JK, et al., “Adolescents’ interest in trying flavoured e-cigarettes,” *Tobacco Control*, 25: ii62–ii66, published online September 15, 2016. Dai, H, et al., “Flavored electronic cigarette use and smoking among youth,” *Pediatrics*, 138(6): November 2016.

¹¹ Food and Drug Administration, *PATH Study Findings Give Insight into Flavored Tobacco, Health Effects of E-Cigarettes, and Adult Use of Cigars and Hookah* (www.fda.gov/tobacco-products/research/path-study-findings-give-insight-flavored-tobacco-health-effects-e-cigarettes-and-adult-use-cigars#references).

¹² Food and Drug Administration, *Preliminary Scientific Evaluation of Possible Public Health Effects of Menthol Versus Nonmenthol Cigarettes* (2013).

¹³ See Food and Drug Administration, *Youth Tobacco Use: Results from the National Youth Tobacco Survey* (www.fda.gov/tobacco-products/youth-and-tobacco/youth-tobacco-use-results-national-youth-tobacco-survey).

ers and importers. In order to bring greater alignment to the regulation of all tobacco products and ensure FDA has the resources necessary to review tobacco products and enforce its regulations, title I would extend user fees to these manufacturers for the first time and also increase the total amount collected annually. This increase was also proposed in the 2020 Trump Administration budget request.¹⁴

In addition, title I requires FDA to finalize rulemaking to implement graphic health warning label requirements for cigarette packages following significant delay and litigation. Studies around the world have shown that graphic health warnings are an effective way to inform consumers about the health risks of smoking and a mechanism to prevent children and other nonsmokers from beginning to smoke. Given the lack of regulatory clarity, the legislation also instructs FDA to issue a rulemaking on the regulation of synthetic nicotine, or nicotine that is not made or derived from tobacco. Title I extends FDA's advertising and sales regulations that currently apply to cigarettes and smokeless tobacco to all tobacco products to ensure e-cigarette and other new tobacco product manufacturers are held to the same advertising and sales requirements that currently apply to traditional cigarettes. This includes prohibiting the distribution of non-tobacco merchandise that bears a tobacco product brand name or logo; prohibiting brand sponsorship of athletic, music, or other concert events by tobacco product manufacturers; prohibiting offering free gifts in consideration of purchasing a tobacco product; and prohibiting advertising or labeling of tobacco products in nontraditional mediums without first notifying FDA.

When introduced, title I also increased the Federal minimum age to purchase tobacco products from age 18 to age 21. This provision, however, was enacted on December 20, 2019, by section 3 of division N of Public Law 116-94, the Further Consolidated Appropriations Act of 2020. In order to update the public health awareness campaigns underway by FDA, title I instructs FDA to modify public health awareness campaigns that are designed to educate at-risk individuals about the harmful effects of tobacco use, particularly for those between the ages of 18 and 21. Title I also requires FDA to provide educational materials to health care providers, members of the public, and law enforcement officials regarding FDA enforcement authorities pertaining to tobacco, including enforcement of the flavor prohibition provision. The purpose of this provision is to ensure individuals are aware of the new provisions of law set in place by H.R. 2339, and to provide proper guidelines for law enforcement officials on the scope and limits of authorities permitted under Federal law. Finally, title I instructs FDA to issue, no later than one year after the date of enactment, regulations concerning recordkeeping protocols for the tracking and tracing of tobacco products. The requirement that FDA issue regulations concerning the tracking and tracing of tobacco products, which would establish a system to follow tobacco products from the manufacturer to a retail setting, was enacted as part of the Family Smoking Prevention and Tobacco Control Act (Tobacco Control

¹⁴A *Budget for a Better America*, Fiscal Year 2020 Budget of the U.S. Government (www.whitehouse.gov/wp-content/uploads/2019/03/budget-fy2020.pdf).

Act). This requirement was intended to help assist in the investigation of illicit trade and diversion, as well as to ensure the integrity of the supply chain, however, FDA has yet to issue the required regulations.

TITLE II—FEDERAL TRADE COMMISSION

Evidence has continually shown that tobacco marketing and promotional activities have an influence on youth usage of tobacco products.¹⁵ In 2012, the Surgeon General highlighted in a report on youth and tobacco use that there is a causal relationship between tobacco advertising and promotion and increased tobacco use.¹⁶ In recent years, the proliferation in use of social media by young people has changed traditional marketing mechanisms as well. One investigation found that platforms such as Instagram, which is the second most popular social media application among teens, was leveraged to promote e-cigarettes to viewers.¹⁷

For these reasons, title II of H.R. 2339 makes it unlawful to market, advertise, or promote any e-cigarette products to individuals under the age of 21 or to market, advertise, promote, or endorse any e-cigarette product without clearly disclosing that the communication is an advertisement. It also requires the Federal Trade Commission (FTC) to issue a report to Congress annually on the domestic sales, advertising, and promotional activities of cigarette, cigar, smokeless tobacco, and e-cigarette manufacturers.

TITLE III—PUBLIC HEALTH PROGRAMS

In order to ensure that medically underserved communities have the necessary tools to effectively quit smoking and successfully undergo tobacco cessation treatment, title III requires CDC to provide education and guidance to develop evidence-based strategies to prevent tobacco use and for smoking cessation. In addition, CDC shall award grants to local public health departments that develop and implement evidence-based strategies for smoking cessation and outreach efforts in medically underserved communities, particularly racial and ethnic minority populations.

TITLE IV—NICOTINE OR VAPING ACCESS PROTECTION AND ENFORCEMENT

H.R. 2339 also ensures FDA has the enforcement authority necessary to deter the sale of tobacco products to young people by increasing the civil penalties applicable for violations of the age restrictions on the sale and distribution of tobacco products. This provision would double the civil penalty amounts under current law for violations under the Tobacco Control Act.

¹⁵See National Cancer Institute, *The Role of the Media in Promoting and Reducing Tobacco Use. Tobacco Control Monograph No. 19* (June 2008); Centers for Disease Control and Prevention, *Executive Summary—Preventing tobacco use among young people: a report of the Surgeon General* (1994).

¹⁶U.S. Health and Human Services, *Preventing Tobacco Use Among Youth and Young Adults: A Report of the Surgeon General* (2012).

¹⁷CNN Health, *#JUUL: How Social Media Hyped Nicotine for a New Generation* (Dec. 19, 2018).

III. COMMITTEE HEARINGS

For the purposes of section 103(i) of H. Res. 6 of the 116th Congress, the following hearing was used to develop or consider H.R. 2339:

The Subcommittee on Health held a legislative hearing on October 11, 2019, entitled “Legislation to Reverse the Youth Tobacco Epidemic” to consider H.R. 2339, the “Reversing the Youth Tobacco Epidemic Act of 2019”. The Subcommittee received testimony from the following witnesses:

- Dorian Fuhrman, Co-founder and Parent, Parents Against Vaping e-cigarettes (PAVe);
- Phillip Gardiner, Dr.P.H., Senior Program Officer, Tobacco Related Disease Research Program, University of California Office of the President;
- Matthew L. Myers, President, Campaign for Tobacco-Free Kids;
- Michael Siegel, M.D., M.P.H., Professor, Department of Community Health Sciences, Boston University School of Public Health; and
- Susanne E. Tanski, M.D., M.P.H., Associate Professor of Pediatrics, American Academy of Pediatrics.

IV. COMMITTEE CONSIDERATION

H.R. 2339, the “Reversing the Youth Tobacco Epidemic Act of 2019”, was introduced on April 18, 2019, by Rep. Frank Pallone, Jr. (D–NJ), and referred to the Committee on Energy and Commerce. The bill was referred to the Subcommittee on Health on April 19, 2019. Following a legislative hearing on the bill, the Subcommittee on Health met in open markup session on Wednesday, November 13, 2019, on H.R. 2339. An amendment in the nature of a substitute (AINS) was offered by Mr. Pallone. The Pallone AINS had five amendments offered to it during its consideration. An amendment offered by Mr. Burgess relating to user fees and reports to Congress was defeated by a record vote of 12 yeas to 17 nays (H-roll call no. 8). Mr. Walden offered an amendment that was defeated by a voice vote. An amendment by Mr. Butterfield and another offered by Mr. Burgess were both agreed to by a voice vote. An amendment offered by Ms. Castor was subsequently withdrawn. The Pallone AINS, amended, was agreed to by a voice vote. The Subcommittee then agreed to a motion by Ms. Eshoo, Chairwoman of the subcommittee, to favorably forward H.R. 2339 to the full Committee, amended, by a voice vote, a quorum being present.

The full Committee on Energy and Commerce met, pursuant to notice, in open markup session on Tuesday, November 19, 2019, to consider H.R. 2339, as amended by the Subcommittee on Health. During committee consideration, 11 amendments were offered to the bill. A bipartisan amendment by Messrs. Ruiz, Bilirakis, and Bucshon was agreed to by a voice vote. Another bipartisan amendment by Messrs. Ruiz and Bucshon was withdrawn. An amendment offered by Ms. Eshoo and another amendment offered by Ms. Clarke of NY were agreed to by a voice vote. An amendment by Mr. Walden was defeated by a voice vote. An amendment offered by Ms. Castor of FL to exempt certain tobacco products from pre-market review under sec. 910 of the Tobacco Control Act. Her amend-

ment was agreed to by a record vote of 29 yeas to 24 nays (roll call no. 49). An amendment by Mr. Burgess was defeated by a record vote of 22 yeas to 31 nays (roll call no. 48); an amendment by Mr. Hudson was defeated by a record vote of 25 yeas to 28 nays (roll call no. 50); an amendment by Mr. Griffith was defeated by a record vote of 22 yeas to 31 nays (roll call no. 47); an amendment by Mr. Burgess was defeated by a record vote of 22 yeas to 29 nays (roll call no. 51); and an amendment offered by Mr. Mullin and Mr. McKinley was defeated by a record vote of 25 yeas to 27 nays (roll call no. 52). At the conclusion of consideration, Mr. Pallone, Chairman of the committee, offered a motion to order H.R. 2339 reported favorably to the House, amended, which was agreed to by a record vote of 28 yeas to 24 nays (roll call no. 53)—Final Passage—a quorum being present.

V. COMMITTEE VOTES

Clause 3(b) of rule XIII of the Rules of the House of Representatives requires the Committee to list each record vote on the motion to report legislation and amendments thereto. The Committee advises that there was one record vote taken on H.R. 2339 during subcommittee consideration, and there were seven record votes taken on H.R. 2339 during full Committee consideration, including a motion made by Mr. Pallone ordering H.R. 2339 favorably reported to the House, amended. The motion on final passage of H.R. 2339 was agreed to by a record vote of 28 yeas to 24 nays. The following are the record votes taken during Committee consideration, including the names of those members voting for and against:

**COMMITTEE ON ENERGY AND COMMERCE
SUBCOMMITTEE ON HEALTH
116th CONGRESS
ROLL CALL VOTE # 8 (HE)**

BILL: H.R. 2339, the "Reversing the Youth Tobacco Epidemic Act of 2019"

AMENDMENT: An amendment to the Pallone AINS offered by Mr. Burgess, No. 1a, to strike the increase for tobacco user fees and insert a requirement that FDA shall submit a written explanation to Congressional Committees as to why FDA has not submitted the required progress reports on implementation of the Tobacco Control Act.

DISPOSITION: NOT AGREED TO by a roll call vote of 12 yeas to 17 nays.

REPRESENTATIVE	YEAS	NAYS	PRESENT	REPRESENTATIVE	YEAS	NAYS	PRESENT
Rep. Eshoo		X		Rep. Burgess	X		
Rep. Engel		X		Rep. Upton	X		
Rep. Butterfield		X		Rep. Shimkus			
Rep. Matsui				Rep. Guthrie	X		
Rep. Castor		X		Rep. Griffith	X		
Rep. Sarbanes		X		Rep. Bilirakis	X		
Rep. Luján		X		Rep. Long			
Rep. Schrader		X		Rep. Bucshon	X		
Rep. Kennedy		X		Rep. Brooks	X		
Rep. Cárdenas		X		Rep. Mullin	X		
Rep. Welch				Rep. Hudson	X		
Rep. Ruiz		X		Rep. Carter	X		
Rep. Dingell		X		Rep. Gianforte	X		
Rep. Kuster		X		Rep. Walden	X		
Rep. Kelly		X					
Rep. Barragán		X					
Rep. Blunt Rochester		X					
Rep. Rush		X					
Rep. Pallone		X					

11/13/2019

COMMITTEE ON ENERGY AND COMMERCE – 116th CONGRESS
ROLL CALL VOTE # 47

BILL: H.R. 2339, the “Reversing the Youth Tobacco Epidemic Act of 2019”

AMENDMENT: Amendment offered by Mr. Griffith, # 7, to amend sec. 907(a) of the Federal Food, Drug, and Cosmetic Act to add prohibition on flavored products that includes marijuana or its derivatives. Retains ‘marihuana’ as defined in section 102 of the Controlled Substances Act.

DISPOSITION: **DEFEATED** by a roll call vote of 22 yeas to 31 nays.

REPRESENTATIVE	YEAS	NAYS	PRESENT	REPRESENTATIVE	YEAS	NAYS	PRESENT
Rep. Pallone		X		Rep. Walden	X		
Rep. Rush		X		Rep. Upton	X		
Rep. Eshoo		X		Rep. Shimkus	X		
Rep. Engel		X		Rep. Burgess	X		
Rep. DeGette		X		Rep. Scalise			
Rep. Doyle		X		Rep. Latta	X		
Rep. Schakowsky		X		Rep. Rodgers	X		
Rep. Butterfield		X		Rep. Guthrie	X		
Rep. Matsui		X		Rep. Olson	X		
Rep. Castor		X		Rep. McKinley	X		
Rep. Sarbanes		X		Rep. Kinzinger	X		
Rep. McNerney		X		Rep. Griffith	X		
Rep. Welch		X		Rep. Bilirakis			
Rep. Luján		X		Rep. Johnson	X		
Rep. Tonko		X		Rep. Long	X		
Rep. Clarke		X		Rep. Buschon	X		
Rep. Loeb sack		X		Rep. Flores	X		
Rep. Schrader		X		Rep. Brooks	X		
Rep. Kennedy		X		Rep. Mullin	X		
Rep. Cárdenas		X		Rep. Hudson	X		
Rep. Ruiz		X		Rep. Walberg	X		
Rep. Peters		X		Rep. Carter	X		
Rep. Dingell		X		Rep. Duncan	X		
Rep. Veasey		X		Rep. Gianforte	X		
Rep. Kuster		X					
Rep. Kelly		X					
Rep. Barragán		X					
Rep. McEachin		X					
Rep. Blunt Rochester		X					
Rep. Soto		X					
Rep. O’Halloran		X					

11/19/2019

COMMITTEE ON ENERGY AND COMMERCE – 116th CONGRESS
ROLL CALL VOTE # 48

BILL: H.R. 2339, the “Reversing the Youth Tobacco Epidemic Act of 2019”

AMENDMENT: Amendment offered by Mr. Burgess, # 3, preventing the increase of user fees to \$812 million unless the FDA submits to the appropriate congressional committees the implementation report required under section 106 of the Tobacco Control Act within 30 days of enactment.

DISPOSITION: **DEFEATED** by a roll call vote of 22 yeas to 31 nays.

REPRESENTATIVE	YEAS	NAYS	PRESENT	REPRESENTATIVE	YEAS	NAYS	PRESENT
Rep. Pallone		X		Rep. Walden	X		
Rep. Rush		X		Rep. Upton	X		
Rep. Eshoo		X		Rep. Shimkus	X		
Rep. Engel		X		Rep. Burgess	X		
Rep. DeGette		X		Rep. Scalise			
Rep. Doyle		X		Rep. Latta	X		
Rep. Schakowsky		X		Rep. Rodgers	X		
Rep. Butterfield		X		Rep. Guthrie	X		
Rep. Matsui		X		Rep. Olson	X		
Rep. Castor		X		Rep. McKinley	X		
Rep. Sarbanes		X		Rep. Kinzinger	X		
Rep. McNerney		X		Rep. Griffith	X		
Rep. Welch		X		Rep. Bilirakis			
Rep. Luján		X		Rep. Johnson	X		
Rep. Tonko		X		Rep. Long	X		
Rep. Clarke		X		Rep. Buschon	X		
Rep. Loeb sack		X		Rep. Flores	X		
Rep. Schrader		X		Rep. Brooks	X		
Rep. Kennedy		X		Rep. Mullin	X		
Rep. Cárdenas		X		Rep. Hudson	X		
Rep. Ruiz		X		Rep. Walberg	X		
Rep. Peters		X		Rep. Carter	X		
Rep. Dingell		X		Rep. Duncan	X		
Rep. Veasey		X		Rep. Gianforte	X		
Rep. Kuster		X					
Rep. Kelly		X					
Rep. Barragán		X					
Rep. McEachin		X					
Rep. Blunt Rochester		X					
Rep. Soto		X					
Rep. O’Halloran		X					

11/19/2019

COMMITTEE ON ENERGY AND COMMERCE – 116th CONGRESS
ROLL CALL VOTE # 49

BILL: H.R. 2339, the “Reversing the Youth Tobacco Epidemic Act of 2019”

AMENDMENT: Amendment offered by Ms. Castor, # 4, manager’s amendment relating to user fees and narrow exemption from premarket review and substantial equivalents application process for certain traditional, handcrafted, premium cigars with a retail price of more than \$12 per cigar.

DISPOSITION: AGREED TO by a roll call vote of 29 yeas to 24 nays.

REPRESENTATIVE	YEAS	NAYS	PRESENT	REPRESENTATIVE	YEAS	NAYS	PRESENT
Rep. Pallone	X			Rep. Walden		X	
Rep. Rush	X			Rep. Upton		X	
Rep. Eshoo	X			Rep. Shimkus		X	
Rep. Engel	X			Rep. Burgess		X	
Rep. DeGette	X			Rep. Scalise			
Rep. Doyle	X			Rep. Latta		X	
Rep. Schakowsky	X			Rep. Rodgers		X	
Rep. Butterfield		X		Rep. Guthrie		X	
Rep. Matsui	X			Rep. Olson		X	
Rep. Castor	X			Rep. McKinley		X	
Rep. Sarbanes	X			Rep. Kinzinger		X	
Rep. McNerney	X			Rep. Griffith		X	
Rep. Welch	X			Rep. Bilirakis			
Rep. Luján	X			Rep. Johnson		X	
Rep. Tonko	X			Rep. Long		X	
Rep. Clarke	X			Rep. Buschon		X	
Rep. Loebsack	X			Rep. Flores		X	
Rep. Schrader	X			Rep. Brooks		X	
Rep. Kennedy	X			Rep. Mullin		X	
Rep. Cárdenas	X			Rep. Hudson		X	
Rep. Ruiz	X			Rep. Walberg		X	
Rep. Peters	X			Rep. Carter		X	
Rep. Dingell	X			Rep. Duncan		X	
Rep. Veasey		X		Rep. Gianforte		X	
Rep. Kuster	X						
Rep. Kelly	X						
Rep. Barragán	X						
Rep. McEachin	X						
Rep. Blunt Rochester	X						
Rep. Soto	X						
Rep. O’Halleran	X						

11/19/2019

COMMITTEE ON ENERGY AND COMMERCE – 116th CONGRESS
ROLL CALL VOTE # 50

BILL: H.R. 2339, the “Reversing the Youth Tobacco Epidemic Act of 2019”

AMENDMENT: Amendment offered by Mr. Hudson, # 5, exempting menthol from the flavor tobacco prohibition under sec. 103(d), allowing menthol as a characterizing flavor that is permitted in tobacco products other than electronic nicotine delivery systems. . The amendment also exempts smokeless tobacco and all cigars—premium cigars and non-premium cigars—from the flavor prohibition provision in its entirety, allowing all these products to contain a characterizing flavor. Limits FDA overall regulatory review and authority over certain traditional large and premium cigars.

DISPOSITION: DEFEATED by a roll call vote of 25 yeas to 28 nays.

REPRESENTATIVE	YEAS	NAYS	PRESENT	REPRESENTATIVE	YEAS	NAYS	PRESENT
Rep. Pallone		X		Rep. Walden	X		
Rep. Rush		X		Rep. Upton	X		
Rep. Eshoo		X		Rep. Shimkus	X		
Rep. Engel		X		Rep. Burgess	X		
Rep. DeGette		X		Rep. Scalise			
Rep. Doyle		X		Rep. Latta	X		
Rep. Schakowsky		X		Rep. Rodgers	X		
Rep. Butterfield	X			Rep. Guthrie	X		
Rep. Matsui		X		Rep. Olson	X		
Rep. Castor		X		Rep. McKinley	X		
Rep. Sarbanes		X		Rep. Kinzinger	X		
Rep. McNerney		X		Rep. Griffith	X		
Rep. Welch		X		Rep. Bilirakis			
Rep. Luján		X		Rep. Johnson	X		
Rep. Tonko		X		Rep. Long	X		
Rep. Clarke	X			Rep. Buschon	X		
Rep. Loeb sack		X		Rep. Flores	X		
Rep. Schrader		X		Rep. Brooks	X		
Rep. Kennedy		X		Rep. Mullin	X		
Rep. Cárdenas		X		Rep. Hudson	X		
Rep. Ruiz		X		Rep. Walberg	X		
Rep. Peters		X		Rep. Carter	X		
Rep. Dingell		X		Rep. Duncan	X		
Rep. Veasey	X			Rep. Gianforte	X		
Rep. Kuster		X					
Rep. Kelly		X					
Rep. Barragán		X					
Rep. McEachin	X						
Rep. Blunt Rochester		X					
Rep. Soto		X					
Rep. O’Halloran		X					

11/19/2019

**COMMITTEE ON ENERGY AND COMMERCE – 116th CONGRESS
ROLL CALL VOTE # 51**

BILL: H.R. 2339, the “Reversing the Youth Tobacco Epidemic Act of 2019”

AMENDMENT: Amendment offered by Mr. Burgess, # 9, to sunset section 104 of the bill, which includes changes to the tobacco user fee allocation, as well as the increase in user fees effective October 1, 2024.

DISPOSITION: **DEFEATED** by a roll call vote of 22 yeas to 29 nays.

REPRESENTATIVE	YEAS	NAYS	PRESENT	REPRESENTATIVE	YEAS	NAYS	PRESENT
Rep. Pallone		X		Rep. Walden	X		
Rep. Rush				Rep. Upton	X		
Rep. Eshoo		X		Rep. Shimkus	X		
Rep. Engel		X		Rep. Burgess	X		
Rep. DeGette		X		Rep. Scalise			
Rep. Doyle		X		Rep. Latta	X		
Rep. Schakowsky		X		Rep. Rodgers	X		
Rep. Butterfield		X		Rep. Guthrie	X		
Rep. Matsui		X		Rep. Olson	X		
Rep. Castor		X		Rep. McKinley	X		
Rep. Sarbanes		X		Rep. Kinzinger	X		
Rep. McNerney		X		Rep. Griffith	X		
Rep. Welch ¹				Rep. Bilirakis			
Rep. Luján		X		Rep. Johnson	X		
Rep. Tonko		X		Rep. Long	X		
Rep. Clarke		X		Rep. Buschon	X		
Rep. Loeb sack		X		Rep. Flores	X		
Rep. Schrader		X		Rep. Brooks	X		
Rep. Kennedy		X		Rep. Mullin	X		
Rep. Cárdenas		X		Rep. Hudson	X		
Rep. Ruiz		X		Rep. Walberg	X		
Rep. Peters		X		Rep. Carter	X		
Rep. Dingell		X		Rep. Duncan	X		
Rep. Veasey		X		Rep. Gianforte	X		
Rep. Kuster		X					
Rep. Kelly		X					
Rep. Barragán		X					
Rep. McEachin		x					
Rep. Blunt Rochester		X					
Rep. Soto		X					
Rep. O’Halloran		X					

11/19/2019

¹ Rep. Welch (D-VT) advised Chairman Pallone and Ranking Member Walden by letter that, in addition to his being a Committee on Energy and Commerce member, he also serves on the House Permanent Select Committee on Intelligence (HPSCI), which is currently conducting an ongoing inquiry into whether President Trump should be impeached. Due to the significance and gravity of this inquiry, his full participation is essential at the HPSCI hearings, which conflicts with the Committee on Energy and Commerce markup on November 19 and 20, 2019, thereby resulting in his absence and missed votes during this Committee markup.

COMMITTEE ON ENERGY AND COMMERCE – 116th CONGRESS
ROLL CALL VOTE # 51

BILL: H.R. 2339, the “Reversing the Youth Tobacco Epidemic Act of 2019”

AMENDMENT: Amendment offered by Mr. Mullin and Mr. McKinley, # 10, to amend the underlying bill to exclude military personnel from the minimum age restrictions for the purchase of tobacco products, as amended in the underlying bill that increases the age to purchase tobacco products from 18 to 21, allowing military personnel to purchase tobacco products at age 18 instead of at age 21.

DISPOSITION: **DEFEATED** by a roll call vote of 25 yeas to 27 nays.

REPRESENTATIVE	YEAS	NAYS	PRESENT	REPRESENTATIVE	YEAS	NAYS	PRESENT
Rep. Pallone		X		Rep. Walden	X		
Rep. Rush		X		Rep. Upton	X		
Rep. Eshoo		X		Rep. Shimkus	X		
Rep. Engel		X		Rep. Burgess	X		
Rep. DeGette		X		Rep. Scalise			
Rep. Doyle		X		Rep. Latta	X		
Rep. Schakowsky		X		Rep. Rodgers	X		
Rep. Butterfield		X		Rep. Guthrie	X		
Rep. Matsui		X		Rep. Olson	X		
Rep. Castor		X		Rep. McKinley	X		
Rep. Sarbanes		X		Rep. Kinzinger	X		
Rep. McNemey		X		Rep. Griffith	X		
Rep. Welch ¹				Rep. Bilirakis			
Rep. Luján		X		Rep. Johnson	X		
Rep. Tonko		X		Rep. Long	X		
Rep. Clarke		X		Rep. Buschon	X		
Rep. Loebsack		X		Rep. Flores		X	
Rep. Schrader		X		Rep. Brooks	X		
Rep. Kennedy		X		Rep. Mullin	X		
Rep. Cárdenas		X		Rep. Hudson	X		
Rep. Ruiz		X		Rep. Walberg	X		
Rep. Peters	X			Rep. Carter	X		
Rep. Dingell		X		Rep. Duncan	X		
Rep. Veasey	X			Rep. Gianforte	X		
Rep. Kuster		X					
Rep. Kelly		X					
Rep. Barragán		X					
Rep. McEachin	X						
Rep. Blunt Rochester		X					
Rep. Soto		X					
Rep. O'Halleran	X						

11/19/2019

¹ Rep. Welch (D-VT) advised Chairman Pallone and Ranking Member Walden by letter that, in addition to his being a Committee on Energy and Commerce member, he also serves on the House Permanent Select Committee on Intelligence (HPSCI), which is currently conducting an ongoing inquiry into whether President Trump should be impeached. Due to the significance and gravity of this inquiry, his full participation is essential at the HPSCI hearings, which conflicts with the Committee on Energy and Commerce markup on November 19 and 20, 2019, thereby resulting in his absence and missed votes during this Committee markup.

COMMITTEE ON ENERGY AND COMMERCE – 116th CONGRESS
ROLL CALL VOTE # 53

BILL: H.R. 2339, the “Reversing the Youth Tobacco Epidemic Act of 2019”

MOTION: A motion by Mr. Pallone of New Jersey to order H.R. 2339 reported favorably to the House, amended (**Final Passage**)

DISPOSITION: **AGREED TO** by a roll call vote of 28 yeas to 24 nays.

REPRESENTATIVE	YEAS	NAYS	PRESENT	REPRESENTATIVE	YEAS	NAYS	PRESENT
Rep. Pallone	X			Rep. Walden		X	
Rep. Rush	X			Rep. Upton	X		
Rep. Eshoo	X			Rep. Shimkus		X	
Rep. Engel	X			Rep. Burgess		X	
Rep. DeGette	X			Rep. Scalise			
Rep. Doyle	X			Rep. Latta		X	
Rep. Schakowsky	X			Rep. Rodgers		X	
Rep. Butterfield		X		Rep. Guthrie		X	
Rep. Matsui	X			Rep. Olson		X	
Rep. Castor	X			Rep. McKinley		X	
Rep. Sarbanes	X			Rep. Kinzinger		X	
Rep. McNerney	X			Rep. Griffith		X	
Rep. Welch ¹				Rep. Bilirakis			
Rep. Luján	X			Rep. Johnson		X	
Rep. Tonko	X			Rep. Long		X	
Rep. Clarke		X		Rep. Buschon		X	
Rep. Loeb sack	X			Rep. Flores		X	
Rep. Schrader	X			Rep. Brooks		X	
Rep. Kennedy	X			Rep. Mullin		X	
Rep. Cárdenas	X			Rep. Hudson		X	
Rep. Ruiz	X			Rep. Walberg		X	
Rep. Peters	X			Rep. Carter		X	
Rep. Dingell	X			Rep. Duncan		X	
Rep. Veasey	X			Rep. Gianforte		X	
Rep. Kuster	X						
Rep. Kelly	X						
Rep. Barragán	X						
Rep. McEachin		X					
Rep. Blunt Rochester	X						
Rep. Soto	X						
Rep. O'Halleran	X						

11/19/2019

¹ Rep. Welch (D-VT) advised Chairman Pallone and Ranking Member Walden by letter that, in addition to his being a Committee on Energy and Commerce member, he also serves on the House Permanent Select Committee on Intelligence (HPSCI), which is currently conducting an ongoing inquiry into whether President Trump should be impeached. Due to the significance and gravity of this inquiry, his full participation is essential at the HPSCI hearings, which conflicts with the Committee on Energy and Commerce markup on November 19 and 20, 2019, thereby resulting in his absence and missed votes during this Committee markup.

VI. OVERSIGHT FINDINGS

Pursuant to clause 3(c)(1) of rule XIII and clause 2(b)(1) of rule X of the Rules of the House of Representatives, the oversight findings and recommendations of the Committee are reflected in the descriptive portion of the report.

VII. NEW BUDGET AUTHORITY, ENTITLEMENT AUTHORITY, AND TAX EXPENDITURES

Pursuant to 3(c)(2) of rule XIII of the Rules of the House of Representatives, the Committee adopts as its own the estimate of new budget authority, entitlement authority, or tax expenditures or revenues contained in the cost estimate prepared by the Director of the Congressional Budget Office pursuant to section 402 of the Congressional Budget Act of 1974.

The Committee has requested but not received from the Director of the Congressional Budget Office a statement as to whether this bill contains any new budget authority, spending authority, credit authority, or an increase or decrease in revenues or tax expenditures.

VIII. FEDERAL MANDATES STATEMENT

The Committee adopts as its own the estimate of Federal mandates prepared by the Director of the Congressional Budget Office pursuant to section 423 of the Unfunded Mandates Reform Act.

IX. STATEMENT OF GENERAL PERFORMANCE GOALS AND OBJECTIVES

Pursuant to clause 3(c)(4) of rule XIII, the general performance goal or objective of this legislation is to enhance the Federal regulatory authorities of the FDA to reverse the youth tobacco epidemic and protect the next generation from a lifetime of nicotine addiction.

X. DUPLICATION OF FEDERAL PROGRAMS

Pursuant to clause 3(c)(5) of rule XIII, no provision of H.R. 2339 is known to be duplicative of another Federal program, including any program that was included in a report to Congress pursuant to section 21 of Public Law 111—139 or the most recent Catalog of Federal Domestic Assistance.

XI. COMMITTEE COST ESTIMATE

Pursuant to clause 3(d)(1) of rule XIII, the Committee adopts as its own the cost estimate prepared by the Director of the Congressional Budget Office pursuant to section 402 of the Congressional Budget Act of 1974.

XII. EARMARKS, LIMITED TAX BENEFITS, AND LIMITED TARIFF BENEFITS

Pursuant to clause 9(e), 9(f), and 9(g) of rule XXI, the Committee finds that H.R. 2339 contains no earmarks, limited tax benefits, or limited tariff benefits.

XIII. ADVISORY COMMITTEE STATEMENT

No advisory committee within the meaning of section 5(b) of the Federal Advisory Committee Act was created by this legislation.

XIV. APPLICABILITY TO LEGISLATIVE BRANCH

The Committee finds that the legislation does not relate to the terms and conditions of employment or access to public services or accommodations within the meaning of section 102(b)(3) of the Congressional Accountability Act.

XV. SECTION-BY-SECTION ANALYSIS OF THE LEGISLATION

Section 1. Short title

Section 1 designates that the short title for this Act may be cited as the “Reversing the Youth Tobacco Epidemic Act of 2019”.

Sec. 2. Table of contents

Section 2 provides the Table of Contents for H.R. 2339, which includes Title I—Food and Drug Administration; Title II—Federal Trade Commission; Title III—Public Health Programs; and Title IV—Nicotine or Vaping Access Protection and Enforcement.

TITLE I—FOOD AND DRUG ADMINISTRATION

Sec. 101. Cigarette graphic health warnings

Section 101 requires that no 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 concerning graphic labeling statements for cigarette packaging, pursuant to section 4(d) of the Federal Cigarette Labeling and Advertising Act. If the Secretary fails to act by March 15, 2020, the proposed rule entitled “Tobacco Products; Required Warnings for Cigarette Packages and Advertisements” shall be treated as a final rule beginning on March 16, 2020.

Sec. 102. Advertising and sales parity for all deemed tobacco products

Section 102 requires that no later than one year after the date of enactment of H.R. 2339, the Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs, publish a final rule amending current regulations concerning advertising and sales under Part 1140 of subchapter K of title 21 of the Code of Federal Regulations to apply to all tobacco products, as applicable. Such rule shall take effect two years after the date of enactment of H.R. 2339.

Sec. 103. Reducing child and adolescent nicotine addiction

Section 103 amends section 901 of FFDCFA to apply to all tobacco products to incorporate into the statute FDA’s authority over all tobacco products, including those that were deemed under the authority of FDA pursuant to the 2016 final deeming rule issued by FDA. Section 103 also amends section 906(d) to increase the minimum age to purchase tobacco products from 18 to 21. Sec. 103(c) amends section 907(a)(1) of the Federal Food, Drug, and Cosmetic Act to prohibit all tobacco products from containing a character-

izing flavor (including menthol, mint, strawberry, grape, orange, clove, cinnamon, pineapple, vanilla, coconut, licorice, cocoa, chocolate, cherry, or coffee) and amends section 910 to prohibit the manufacture and sale of all flavored ENDS product 30 days after the date of enactment of H.R. 2339.

Section 103(c) also states that the Secretary shall not issue a marketing order for a flavored ENDS product unless the manufacturer has demonstrated that 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 such electronic nicotine delivery system is not more harmful to users than an electronic nicotine delivery system that does not contain any characterizing flavors.

Sec. 104. Prohibition against remote retail sales

Section 104 requires that no later than 18 months after the date of enactment of H.R. 2339, the Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs, shall publish a final rule prohibiting the retail sale of all tobacco products other than retail sales through a direct, face-to-face exchange between a retailer and consumer. Section 104 includes an exception for certain cigar tobacco products but requires FDA to promulgate regulations regarding the sale and distribution of excepted cigar tobacco products when sold other than through direct, face-to-face exchanges.

Sec. 105. Fees applicable to all tobacco products

Section 105 increases the total annual amount of user fees applicable to tobacco products from \$712,000,000 to \$812,000,000 beginning in fiscal year 2020. For each year thereafter, this amount increases by the total percentage change in the consumer price index for all urban consumers. In addition, section 105 applies user fees to all classes of tobacco products and instructs FDA to determine a formula for the allocation user fees to be paid by tobacco product manufacturers or importers that is equal to the percentage of gross domestic sales in the previous calendar year, as reported by tobacco product manufacturers to the FDA.

Sec. 106. Regulation of products containing synthetic nicotine

Section 106 requires that no later than one year after the date of enactment of H.R. 2339, the Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs, shall issue an interim final rule on the regulation of synthetic nicotine, or nicotine that is not made or derived from tobacco. Section 106 then requires that this rule be finalized no later than two years after the date of enactment of H.R. 2339.

Sec. 107. Update to youth tobacco prevention public awareness campaigns

Section 107 requires the Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs, to review all public awareness campaigns designed to educate at-risk individuals about the harmful effects of tobacco use and modify such

campaigns, as applicable, to include materials designed for individuals aged 18 to 21.

Sec. 108. Exemption from premarket approval of certain tobacco products

Section 108 amends section 910(a)(2) of FFDCA to exempt certain cigar tobacco products from the premarket review requirements under section 910 of the Tobacco Control Act beginning on the date of enactment of H.R. 2339 and ending on September 30, 2028. Section 108 defines these exempted products as a tobacco product that 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) is made by combining manually the wrapper, filler, and binder and is capped by hand, or 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 and coupons) per cigar of no less than \$12 for calendar years 2019 and 2020 and indexed to inflation.

Section 108 states that the Secretary shall withdraw any applicable exemption for such cigar products if certain conditions are met, including a determination that the use of the exempted tobacco product has resulted in an emerging public health threat; data from the National Youth Tobacco Survey (or successor survey) identifies a rise in youth usage of exempted tobacco products; or if the Secretary determines that a tobacco product no longer meets the criteria for the exemption.

Section 108 also requires the Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs, to enter into an agreement with the National Academies of Sciences, Engineering, and Medicine to conduct a study and report to Congress on the public health impact of exempting certain cigar tobacco products from the requirements under section 910 of FFDCA and the youth usage of such products. The report shall be submitted to Congress no later than December 31, 2026.

Sec. 109. Public education

Section 109 amends section 906 of FFDCA to require that not later than six months after the date of enactment of H.R. 2339, 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 the authority of FDA with respect to the enforcement of regulations of tobacco products, including the prohibition on characterizing flavors and the public health impact of tobacco products with characterizing flavors.

Sec. 110. Regulations for recordkeeping concerning tracking and tracing

Section 110 requires that no later than one year after the date of enactment of H.R. 2339, the Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs,

shall publish a proposed rule on the recordkeeping requirements for tracking and tracing tobacco products under section 920(b) of the Federal Food, Drug, and Cosmetic Act. Section 110 then requires these regulations to be finalized no later than two years after the date of enactment of H.R. 2339.

TITLE II—FEDERAL TRADE COMMISSION

Sec. 201. Advertising of tobacco products

Section 201 makes it unlawful to market, advertise, or promote any electronic nicotine delivery system in a manner that appeals to an individual under the age of 21 or market, advertise, promote, endorse, or 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. Section 201 also gives FTC the authority to issue rules under notice-and-comment rulemaking to implement these prohibitions. It also allows FTC and state attorneys general to enforce the advertising prohibitions and seek civil penalties for violations. In addition, Section 201 also requires FTC to issue a report to Congress within two years, and annually thereafter, on the domestic sales, advertising, and promotional activity of cigarette, cigar, smokeless tobacco, and e-cigarette manufacturers.

TITLE III—PUBLIC HEALTH PROGRAMS

Sec. 301. Outreach to medically underserved communities

Section 301 requires the Secretary to ensure that programs at CDC related to outreach to medically underserved communities, including racial and ethnic minority populations, include efforts to educate and provide guidance on evidence-based strategies to prevent tobacco, e-cigarette, and nicotine addiction, as well as smoking cessation and cessation from the use of e-cigarettes and ENDS.

Sec. 302. Demonstration grant program to develop strategies for smoking cessation in medically underserved communities

Section 302 directs the CDC to establish a demonstration program to award grants to State, local, Tribal, or territorial public health departments to support the development of improved evidence-based strategies for smoking cessation in medically underserved communities, particularly racial and ethnic minority populations. Section 302 authorizes to be appropriated \$3,000,000 for each of fiscal years 2020 through 2024 for this demonstration program.

TITLE IV—NICOTINE OR VAPING ACCESS PROTECTION AND ENFORCEMENT

Section 401. Short title

Section 401 designates that the short title of title IV 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

Section 402 amends section 103(q)(2) of the Tobacco Control Act to increase the civil penalties applicable to certain violations of restrictions on sale and distribution of tobacco products.

Sec. 403. Study and report on e-cigarettes

Section 403 requires the Comptroller General of the United States to study and issue a report to Congress not later than five years after the date of enactment of H.R. 2339 on the relationship between e-cigarettes and tobacco cessation; the perception of the harmful effects of e-cigarettes; and the effects of secondhand exposure to smoke from e-cigarettes.

CHANGES IN EXISTING LAW MADE BY THE BILL, AS REPORTED

In compliance with clause 3(e) of rule XIII of the Rules of the House of Representatives, changes in existing law made by the bill, as reported, are shown as follows (existing law proposed to be omitted is enclosed in black brackets, new matter is printed in italics, and existing law in which no change is proposed is shown in roman):

FEDERAL CIGARETTE LABELING AND ADVERTISING ACT

* * * * *

SEC. 4. LABELING.

(a) LABEL REQUIREMENTS.—

(1) IN GENERAL.—It shall be unlawful for any person to manufacture, package, sell, offer to sell, distribute, or import for sale or distribution within the United States any cigarettes the package of which fails to bear, in accordance with the requirements of this section, one of the following labels:

WARNING: Cigarettes are addictive.

WARNING: Tobacco smoke can harm your children.

WARNING: Cigarettes cause fatal lung disease.

WARNING: Cigarettes cause cancer.

WARNING: Cigarettes cause strokes and heart disease.

WARNING: Smoking during pregnancy can harm your baby.

WARNING: Smoking can kill you.

WARNING: Tobacco smoke causes fatal lung disease in nonsmokers.

WARNING: Quitting smoking now greatly reduces serious risks to your health.

(2) PLACEMENT; TYPOGRAPHY; ETC.—Each label statement required by paragraph (1) shall be located in the upper portion of the front and rear panels of the package, directly on the package underneath the cellophane or other clear wrapping. Each label statement shall comprise the top 50 percent of the front and rear panels of the package. The word “WARNING” shall appear in capital letters and all text shall be in conspicuous and legible 17-point type, unless the text of the label statement would occupy more than 70 percent of such area, in

which case the text may be in a smaller conspicuous and legible type size, provided that at least 60 percent of such area is occupied by required text. The text shall be black on a white background, or white on a black background, in a manner that contrasts, by typography, layout, or color, with all other printed material on the package, in an alternating fashion under the plan submitted under subsection (c).

(3) DOES NOT APPLY TO FOREIGN DISTRIBUTION.—The provisions of this subsection do not apply to a tobacco product manufacturer or distributor of cigarettes which does not manufacture, package, or import cigarettes for sale or distribution within the United States.

(4) APPLICABILITY TO RETAILERS.—A retailer of cigarettes shall not be in violation of this subsection for packaging that—

(A) contains a warning label;

(B) is supplied to the retailer by a license- or permit-holding tobacco product manufacturer, importer, or distributor; and

(C) is not altered by the retailer in a way that is material to the requirements of this subsection.

(b) ADVERTISING REQUIREMENTS.—

(1) IN GENERAL.—It shall be unlawful for any tobacco product manufacturer, importer, distributor, or retailer of cigarettes to advertise or cause to be advertised within the United States any cigarette unless its advertising bears, in accordance with the requirements of this section, one of the labels specified in subsection (a).

(2) TYPOGRAPHY, ETC.—Each label statement required by subsection (a) in cigarette advertising shall comply with the standards set forth in this paragraph. For press and poster advertisements, each such statement and (where applicable) any required statement relating to tar, nicotine, or other constituent (including a smoke constituent) yield shall comprise at least 20 percent of the area of the advertisement and shall appear in a conspicuous and prominent format and location at the top of each advertisement within the trim area. The Secretary may revise the required type sizes in such area in such manner as the Secretary determines appropriate. The word “WARNING” shall appear in capital letters, and each label statement shall appear in conspicuous and legible type. The text of the label statement shall be black if the background is white and white if the background is black, under the plan submitted under subsection (c). The label statements shall be enclosed by a rectangular border that is the same color as the letters of the statements and that is the width of the first downstroke of the capital “W” of the word “WARNING” in the label statements. The text of such label statements shall be in a typeface pro rata to the following requirements: 45-point type for a whole-page broadsheet newspaper advertisement; 39-point type for a half-page broadsheet newspaper advertisement; 39-point type for a whole-page tabloid newspaper advertisement; 27-point type for a half-page tabloid newspaper advertisement; 31.5-point type for a double page spread magazine or whole-page magazine advertisement; 22.5-point type for a 28 centimeter by 3 column advertisement; and 15-point type for a

20 centimeter by 2 column advertisement. The label statements shall be in English, except that—

(A) in the case of an advertisement that appears in a newspaper, magazine, periodical, or other publication that is not in English, the statements shall appear in the predominant language of the publication; and

(B) in the case of any other advertisement that is not in English, the statements shall appear in the same language as that principally used in the advertisement.

(3) MATCHBOOKS.—Notwithstanding paragraph (2), for matchbooks (defined as containing not more than 20 matches) customarily given away with the purchase of tobacco products, each label statement required by subsection (a) may be printed on the inside cover of the matchbook.

(4) ADJUSTMENT BY SECRETARY.—The Secretary may, through a rulemaking under section 553 of title 5, United States Code, adjust the format and type sizes for the label statements required by this section; the text, format, and type sizes of any required tar, nicotine yield, or other constituent (including smoke constituent) disclosures; or the text, format, and type sizes for any other disclosures required under the Federal Food, Drug, and Cosmetic Act. The text of any such label statements or disclosures shall be required to appear only within the 20 percent area of cigarette advertisements provided by paragraph (2). The Secretary shall promulgate regulations which provide for adjustments in the format and type sizes of any text required to appear in such area to ensure that the total text required to appear by law will fit within such area.

(c) MARKETING REQUIREMENTS.—

(1) RANDOM DISPLAY.—The label statements specified in subsection (a)(1) shall be randomly displayed in each 12-month period, in as equal a number of times as is possible on each brand of the product and be randomly distributed in all areas of the United States in which the product is marketed in accordance with a plan submitted by the tobacco product manufacturer, importer, distributor, or retailer and approved by the Secretary.

(2) ROTATION.—The label statements specified in subsection (a)(1) shall be rotated quarterly in alternating sequence in advertisements for each brand of cigarettes in accordance with a plan submitted by the tobacco product manufacturer, importer, distributor, or retailer to, and approved by, the Secretary.

(3) REVIEW.—The Secretary shall review each plan submitted under paragraph (2) and approve it if the plan—

(A) will provide for the equal distribution and display on packaging and the rotation required in advertising under this subsection; and

(B) assures that all of the labels required under this section will be displayed by the tobacco product manufacturer, importer, distributor, or retailer at the same time.

(4) APPLICABILITY TO RETAILERS.—This subsection and subsection (b) apply to a retailer only if that retailer is responsible for or directs the label statements required under this section except that this paragraph shall not relieve a retailer of liabil-

ity if the retailer displays, in a location open to the public, an advertisement that does not contain a warning label or has been altered by the retailer in a way that is material to the requirements of this subsection and subsection (b).

(d) GRAPHIC LABEL STATEMENTS.—[Not later than 24 months after the date of enactment of the Family Smoking Prevention and Tobacco Control Act, the Secretary] *The Secretary* shall issue regulations that require color graphics depicting the negative health consequences of smoking to accompany the label statements specified in subsection (a)(1). The Secretary may adjust the type size, text and format of the label statements specified in subsections (a)(2) and (b)(2) as the Secretary determines appropriate so that both the graphics and the accompanying label statements are clear, conspicuous, legible and appear within the specified area.

(d) CHANGE IN REQUIRED STATEMENTS.—The Secretary through a rulemaking conducted under section 553 of title 5, United States Code, may adjust the format, type size, color graphics, and text of any of the label requirements, or establish the format, type size, and text of any other disclosures required under the Federal Food, Drug, and Cosmetic Act, if the Secretary finds that such a change would promote greater public understanding of the risks associated with the use of tobacco products.

(e) TAR, NICOTINE, AND OTHER SMOKE CONSTITUENT DISCLOSURE.—

(1) IN GENERAL.—The Secretary shall, by a rulemaking conducted under section 553 of title 5, United States Code, determine (in the Secretary's sole discretion) whether cigarette and other tobacco product manufacturers shall be required to include in the area of each cigarette advertisement specified by subsection (b) of this section, or on the package label, or both, the tar and nicotine yields of the advertised or packaged brand. Any such disclosure shall be in accordance with the methodology established under such regulations, shall conform to the type size requirements of subsection (b) of this section, and shall appear within the area specified in subsection (b) of this section.

(2) RESOLUTION OF DIFFERENCES.—Any differences between the requirements established by the Secretary under paragraph (1) and tar and nicotine yield reporting requirements established by the Federal Trade Commission shall be resolved by a memorandum of understanding between the Secretary and the Federal Trade Commission.

(3) CIGARETTE AND OTHER TOBACCO PRODUCT CONSTITUENTS.—In addition to the disclosures required by paragraph (1), the Secretary may, under a rulemaking conducted under section 553 of title 5, United States Code, prescribe disclosure requirements regarding the level of any cigarette or other tobacco product constituent including any smoke constituent. Any such disclosure may be required if the Secretary determines that disclosure would be of benefit to the public health, or otherwise would increase consumer awareness of the health consequences of the use of tobacco products, except that no such prescribed disclosure shall be required on the face of any cigarette package or advertisement. Nothing in this section shall prohibit the Secretary from requiring such prescribed dis-

closure through a cigarette or other tobacco product package or advertisement insert, or by any other means under the Federal Food, Drug, and Cosmetic Act.

(4) RETAILERS.—This subsection applies to a retailer only if that retailer is responsible for or directs the label statements required under this section.

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FEDERAL FOOD, DRUG, AND COSMETIC ACT

* * * * *

CHAPTER III—PROHIBITED ACTS AND PENALTIES

PROHIBITED ACTS

SEC. 301. The following acts and the causing thereof are hereby prohibited:

(a) The introduction or delivery for introduction into interstate commerce of any food, drug, device, tobacco product, or cosmetic that is adulterated or misbranded.

(b) The adulteration or misbranding of any food, drug, device, tobacco product, or cosmetic in interstate commerce.

(c) The receipt in interstate commerce of any food, drug, device, tobacco product, or cosmetic that is adulterated or misbranded, and the delivery or proffered delivery thereof for pay or otherwise.

(d) The introduction or delivery for introduction into interstate commerce of any article in violation of section 404, 415, 505, or 564.

(e) The refusal to permit access to or copying of any record as required by section 412, 414, 417(j), 416, 504, 564, 703, 704(a), 760, or 761; or the failure to establish or maintain any record, or make any report, required under section 412, 414(b), 417, 416, 504, 505 (i) or (k), 512(a)(4)(C), 512 (j), (l) or (m), 572(i), 515(f), 519, 564, 760, 761, 909, or 920 or the refusal to permit access to or verification or copying of any such required record; or the violation of any recordkeeping requirement under section 204 of the FDA Food Safety Modernization Act (except when such violation is committed by a farm).

(f) The refusal to permit entry or inspection as authorized by section 704.

(g) The manufacture within any Territory of any food, drug, device, tobacco product, or cosmetic that is adulterated or misbranded.

(h) The giving of a guaranty or undertaking referred to in section 303(c)(2), which guaranty or undertaking is false, except by a person who relied upon a guaranty or undertaking to the same effect signed by, and containing the name and address of, the person residing in the United States from whom he received in good faith the food, drug, device, tobacco product, or cosmetic; or the giving of a guaranty or undertaking referred to in section 303(c)(3), which guaranty or undertaking is false.

(i)(1) Forging, counterfeiting, simulating, or falsely representing, or without proper authority using any mark, stamp, tag, label, or

other identification device authorized or required by regulations promulgated under the provisions of section 404 or 721.

(2) Making, selling, disposing of, or keeping in possession, control, or custody, or concealing any punch, die, plate, stone, or other thing designed to print, imprint, or reproduce the trademark, trade name, or other identifying mark, imprint, or device of another or any likeness of any of the foregoing upon any drug or container or labeling thereof so as to render such drugs a counterfeit drug.

(3) The doing of any act which causes a drug to be a counterfeit drug, or the sale or dispensing, or the holding for sale or dispensing, of a counterfeit drug.

(j) The using by any person to his own advantage, or revealing, other than to the Secretary or officers or employees of the Department, or to the courts when relevant in any judicial proceeding under this Act, any information acquired under authority of section 404, 409, 412, 414, 505, 510, 512, 513, 514, 515, 516, 518, 519, 520, 571, 572, 573, 704, 708, 721, 904, 905, 906, 907, 908, 909, or 920(b) concerning any method or process which as a trade secret is entitled to protection; or the violating of section 408(i)(2) or any regulation issued under that section.. This paragraph does not authorize the withholding of information from either House of Congress or from, to the extent of matter within its jurisdiction, any committee or subcommittee of such committee or any joint committee of Congress or any subcommittee of such joint committee.

(k) The alteration, mutilation, destruction, obliteration, or removal of the whole or any part of the labeling of, or the doing of any other act with respect to, a food, drug, device, tobacco product, or cosmetic, if such act is done while such article is held for sale (whether or not the first sale) after shipment in interstate commerce and results in such article being adulterated or misbranded.

(m) The sale or offering for sale of colored oleomargarine or colored margarine, or the possession or serving of colored oleomargarine or colored margarine in violation of section 407(b) or 407(c).

(n) The using, in labeling, advertising or other sales promotion of any reference to any report or analysis furnished in compliance with section 704.

(o) In the case of a prescription drug distributed or offered for sale in interstate commerce, the failure of the manufacturer, packer, or distributor thereof to maintain for transmittal, or to transmit, to any practitioner licensed by applicable State law to administer such drug who makes written request for information as to such drug, true and correct copies of all printed matter which is required to be included in any package in which that drug is distributed or sold, or such other printed matter as is approved by the Secretary. Nothing in this paragraph shall be construed to exempt any person from any labeling requirement imposed by or under other provisions of this Act.

(p) The failure to register in accordance with section 510 or 905, the failure to provide any information required by section 510(j), 510(k), 905(i), or 905(j), or the failure to provide a notice required by section 510(j)(2) or 905(i)(3).

(q)(1) The failure or refusal—

(A) to comply with any requirement prescribed under section 518, 520(g), 903(b), 907, 908, or 915;

(B) to furnish any notification or other material or information required by or under section 519, 520(g), 904, 909, 919(b)(2)(D), or 920; or

(C) to comply with a requirement under section 522 or 913.

(2) With respect to any device or tobacco product, the submission of any report that is required by or under this Act that is false or misleading in any material respect.

(r) The movement of a device, drug, or tobacco product in violation of an order under section 304(g) or the removal or alteration of any mark or label required by the order to identify the device, drug, or tobacco product as detained.

(s) The failure to provide the notice required by section 412(c) or 412(e), the failure to make the reports required by section 412(f)(1)(B), the failure to retain the records required by section 412(b)(4), or the failure to meet the requirements prescribed under section 412(f)(3).

(t) The importation of a drug in violation of section 801(d)(1), the sale, purchase, or trade of a drug or drug sample or the offer to sell, purchase, or trade a drug or drug sample in violation of section 503(c), the sale, purchase, or trade of a coupon, the offer to sell, purchase, or trade such a coupon, or the counterfeiting of such a coupon in violation of section 503(c)(2), the distribution of a drug sample in violation of section 503(d) or the failure to otherwise comply with the requirements of section 503(d), the distribution of drugs in violation of section 503(e), failure to comply with the requirements under section 582, the failure to comply with the requirements under section 584, as applicable, or the failure to otherwise comply with the requirements of section 503(e).

(u) The failure to comply with any requirements of the provisions of, or any regulations or orders of the Secretary, under section 512(a)(4)(A), 512(a)(4)(D), or 512(a)(5).

(v) The introduction or delivery for introduction into interstate commerce of a dietary supplement that is unsafe under section 413.

(w) The making of a knowingly false statement in any statement, certificate of analysis, record, or report required or requested under section 801(d)(3); the failure to submit a certificate of analysis as required under such section; the failure to maintain records or to submit records or reports as required by such section; the release into interstate commerce of any article or portion thereof imported into the United States under such section or any finished product made from such article or portion, except for export in accordance with section 801(e) or 802, or with section 351(h) of the Public Health Service Act; or the failure to so export or to destroy such an article or portions thereof, or such a finished product.

(x) The falsification of a declaration of conformity submitted under section 514(c) or the failure or refusal to provide data or information requested by the Secretary under paragraph (3) of such section.

(y) In the case of a drug, device, or food—

(1) the submission of a report or recommendation by a person accredited under section 523 that is false or misleading in any material respect;

(2) the disclosure by a person accredited under section 523 of confidential commercial information or any trade secret

without the express written consent of the person who submitted such information or secret to such person; or

(3) the receipt by a person accredited under section 523 of a bribe in any form or the doing of any corrupt act by such person associated with a responsibility delegated to such person under this Act.

(z) The dissemination of information in violation of section 551.

(aa) The importation of a prescription drug in violation of section 804, the falsification of any record required to be maintained or provided to the Secretary under such section, or any other violation of regulations under such section.

(bb) The transfer of an article of food in violation of an order under section 304(h), or the removal or alteration of any mark or label required by the order to identify the article as detained.

(cc) The importing or offering for import into the United States of an article of food or a drug by, with the assistance of, or at the direction of, a person debarred from such activity under section 306(b)(3).

(dd) The failure to register in accordance with section 415.

(ee) The importing or offering for import into the United States of an article of food in violation of the requirements under section 801(m).

(ff) The importing or offering for import into the United States of a drug or device with respect to which there is a failure to comply with a request of the Secretary to submit to the Secretary a statement under section 801(o).

(gg) The knowing failure to comply with paragraph (7)(E) of section 704(g); the knowing inclusion by a person accredited under paragraph (2) of such section of false information in an inspection report under paragraph (7)(A) of such section; or the knowing failure of such a person to include material facts in such a report.

(hh) The failure by a shipper, carrier by motor vehicle or rail vehicle, receiver, or any other person engaged in the transportation of food to comply with the sanitary transportation practices prescribed by the Secretary under section 416.

(ii) The falsification of a report of a serious adverse event submitted to a responsible person (as defined under section 760 or 761) or the falsification of a serious adverse event report (as defined under section 760 or 761) submitted to the Secretary.

(jj)(1) The failure to submit the certification required by section 402(j)(5)(B) of the Public Health Service Act, or knowingly submitting a false certification under such section.

(2) The failure to submit clinical trial information required under subsection (j) of section 402 of the Public Health Service Act.

(3) The submission of clinical trial information under subsection (j) of section 402 of the Public Health Service Act that is false or misleading in any particular under paragraph (5)(D) of such subsection (j).

(kk) The dissemination of a television advertisement without complying with section 503B.

(ll) The introduction or delivery for introduction into interstate commerce of any food to which has been added a drug approved under section 505, a biological product licensed under section 351 of the Public Health Service Act, or a drug or a biological product for which substantial clinical investigations have been instituted

and for which the existence of such investigations has been made public, unless—

(1) such drug or such biological product was marketed in food before any approval of the drug under section 505, before licensure of the biological product under such section 351, and before any substantial clinical investigations involving the drug or the biological product have been instituted;

(2) the Secretary, in the Secretary's discretion, has issued a regulation, after notice and comment, approving the use of such drug or such biological product in the food;

(3) the use of the drug or the biological product in the food is to enhance the safety of the food to which the drug or the biological product is added or applied and not to have independent biological or therapeutic effects on humans, and the use is in conformity with—

(A) a regulation issued under section 409 prescribing conditions of safe use in food;

(B) a regulation listing or affirming conditions under which the use of the drug or the biological product in food is generally recognized as safe;

(C) the conditions of use identified in a notification to the Secretary of a claim of exemption from the premarket approval requirements for food additives based on the notifier's determination that the use of the drug or the biological product in food is generally recognized as safe, provided that the Secretary has not questioned the general recognition of safety determination in a letter to the notifier;

(D) a food contact substance notification that is effective under section 409(h); or

(E) such drug or biological product had been marketed for smoking cessation prior to the date of the enactment of the Food and Drug Administration Amendments Act of 2007; or

(4) the drug is a new animal drug whose use is not unsafe under section 512.

(mm) The failure to submit a report or provide a notification required under section 417(d).

(nn) The falsification of a report or notification required under section 417(d).

(oo) The sale of tobacco products in violation of a no-tobacco-sale order issued under section 303(f).

(pp) The introduction or delivery for introduction into interstate commerce of a tobacco product in violation of section 911.

(qq)(1) Forging, counterfeiting, simulating, or falsely representing, or without proper authority using any mark, stamp (including tax stamp), tag, label, or other identification device upon any tobacco product or container or labeling thereof so as to render such tobacco product a counterfeit tobacco product.

(2) Making, selling, disposing of, or keeping in possession, control, or custody, or concealing any punch, die, plate, stone, or other item that is designed to print, imprint, or reproduce the trademark, trade name, or other identifying mark, imprint, or device of another or any likeness of any of the foregoing upon any tobacco prod-

uct or container or labeling thereof so as to render such tobacco product a counterfeit tobacco product.

(3) The doing of any act that causes a tobacco product to be a counterfeit tobacco product, or the sale or dispensing, or the holding for sale or dispensing, of a counterfeit tobacco product.

(rr) The charitable distribution of tobacco products.

(ss) The failure of a manufacturer or distributor to notify the Attorney General and the Secretary of the Treasury of their knowledge of tobacco products used in illicit trade.

(tt) Making any express or implied statement or representation directed to consumers with respect to a tobacco product, in a label or labeling or through the media or advertising, that either conveys, or misleads or would mislead consumers into believing, that—

(1) the product is approved by the Food and Drug Administration;

(2) the Food and Drug Administration deems the product to be safe for use by consumers;

(3) the product is endorsed by the Food and Drug Administration for use by consumers; or

(4) the product is safe or less harmful by virtue of—

(A) its regulation or inspection by the Food and Drug Administration; or

(B) its compliance with regulatory requirements set by the Food and Drug Administration;

including any such statement or representation rendering the product misbranded under section 903.

(uu) The operation of a facility that manufactures, processes, packs, or holds food for sale in the United States if the owner, operator, or agent in charge of such facility is not in compliance with section 418.

(vv) The failure to comply with the requirements under section 419.

(ww) The failure to comply with section 420.

(xx) The refusal or failure to follow an order under section 423.

(yy) The knowing and willful failure to comply with the notification requirement under section 417(h).

(zz) The importation or offering for importation of a food if the importer (as defined in section 805) does not have in place a foreign supplier verification program in compliance with such section 805.

(aaa) The failure to register in accordance with section 801(s).

(bbb) The failure to notify the Secretary in violation of section 568.

(ccc)(1) The resale of a compounded drug that is labeled “not for resale” in accordance with section 503B.

(2) With respect to a drug to be compounded pursuant to section 503A or 503B, the intentional falsification of a prescription, as applicable.

(3) The failure to report drugs or adverse events by an entity that is registered in accordance with subsection (b) of section 503B.

(ddd)(1) The manufacture or the introduction or delivery for introduction into interstate commerce of a rinse-off cosmetic that contains intentionally-added plastic microbeads.

(2) In this paragraph—

(A) the term “plastic microbead” means any solid plastic particle that is less than five millimeters in size and is intended to be used to exfoliate or cleanse the human body or any part thereof; and

(B) the term “rinse-off cosmetic” includes toothpaste.

(eee) The failure to comply with any order issued under section 569D.

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CHAPTER IX—TOBACCO PRODUCTS

SEC. 900. DEFINITIONS.

In this chapter:

(1) **ADDITIVE.**—The term “additive” means any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristic of any tobacco product (including any substances intended for use as a flavoring or coloring or in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding), except that such term does not include tobacco or a pesticide chemical residue in or on raw tobacco or a pesticide chemical.

(2) **BRAND.**—The term “brand” means a variety of tobacco product distinguished by the tobacco used, tar content, nicotine content, flavoring used, size, filtration, packaging, logo, registered trademark, brand name, identifiable pattern of colors, or any combination of such attributes.

(3) **CIGARETTE.**—The term “cigarette”—

(A) means a product that—

(i) is a tobacco product; and

(ii) meets the definition of the term “cigarette” in section 3(1) of the Federal Cigarette Labeling and Advertising Act; and

(B) includes tobacco, in any form, that is functional in the product, which, because of its appearance, the type of tobacco used in the filler, or its packaging and labeling, is likely to be offered to, or purchased by, consumers as a cigarette or as roll-your-own tobacco.

(4) **CIGARETTE TOBACCO.**—The term “cigarette tobacco” means any product that consists of loose tobacco that is intended for use by consumers in a cigarette. Unless otherwise stated, the requirements applicable to cigarettes under this chapter shall also apply to cigarette tobacco.

(5) **COMMERCE.**—The term “commerce” has the meaning given that term by section 3(2) of the Federal Cigarette Labeling and Advertising Act.

(6) **COUNTERFEIT TOBACCO PRODUCT.**—The term “counterfeit tobacco product” means a tobacco product (or the container or labeling of such a product) that, without authorization, bears the trademark, trade name, or other identifying mark, imprint, or device, or any likeness thereof, of a tobacco product listed in a registration under section 905(i)(1).

(7) **DISTRIBUTOR.**—The term “distributor” as regards a tobacco product means any person who furthers the distribution of a tobacco product, whether domestic or imported, at any

point from the original place of manufacture to the person who sells or distributes the product to individuals for personal consumption. Common carriers are not considered distributors for purposes of this chapter.

(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).

[(8)] (9) *ILLICIT TRADE.*—The term “illicit trade” means any practice or conduct prohibited by law which relates to production, shipment, receipt, possession, distribution, sale, or purchase of tobacco products including any practice or conduct intended to facilitate such activity.

[(9)] (10) *INDIAN COUNTRY.*—The term “Indian country” has the meaning given such term in section 1151 of title 18, United States Code.

[(10)] (11) *INDIAN TRIBE.*—The term “Indian tribe” has the meaning given such term in section 4(e) of the Indian Self-Determination and Education Assistance Act.

[(11)] (12) *LITTLE CIGAR.*—The term “little cigar” means a product that—

(A) is a tobacco product; and

(B) meets the definition of the term “little cigar” in section 3(7) of the Federal Cigarette Labeling and Advertising Act.

[(12)] (13) *NICOTINE.*—The term “nicotine” means the chemical substance named 3-(1-Methyl-2-pyrrolidinyl) pyridine or CHN, including any salt or complex of nicotine.

[(13)] (14) *PACKAGE.*—The term “package” means a pack, box, carton, or container of any kind or, if no other container, any wrapping (including cellophane), in which a tobacco product is offered for sale, sold, or otherwise distributed to consumers.

[(14)] (15) *RETAILER.*—The term “retailer” means any person, government, or entity who sells tobacco products to individuals for personal consumption, or who operates a facility where self-service displays of tobacco products are permitted.

[(15)] (16) *ROLL-YOUR-OWN TOBACCO.*—The term “roll-your-own tobacco” means any tobacco product which, because of its appearance, type, packaging, or labeling, is suitable for use and likely to be offered to, or purchased by, consumers as tobacco for making cigarettes.

[(16)] (17) *SMALL TOBACCO PRODUCT MANUFACTURER.*—The term “small tobacco product manufacturer” means a tobacco

product manufacturer that employs fewer than 350 employees. For purposes of determining the number of employees of a manufacturer under the preceding sentence, the employees of a manufacturer are deemed to include the employees of each entity that controls, is controlled by, or is under common control with such manufacturer.

[(17)] (18) SMOKE CONSTITUENT.—The term “smoke constituent” means any chemical or chemical compound in mainstream or sidestream tobacco smoke that either transfers from any component of the cigarette to the smoke or that is formed by the combustion or heating of tobacco, additives, or other component of the tobacco product.

[(18)] (19) SMOKELESS TOBACCO.—The term “smokeless tobacco” means any tobacco product that consists of cut, ground, powdered, or leaf tobacco and that is intended to be placed in the oral or nasal cavity.

[(19)] (20) STATE; TERRITORY.—The terms “State” and “Territory” shall have the meanings given to such terms in section 201.

[(20)] (21) TOBACCO PRODUCT MANUFACTURER.—The term “tobacco product manufacturer” means any person, including any repacker or relabeler, who—

(A) manufactures, fabricates, assembles, processes, or labels a tobacco product; or

(B) imports a finished tobacco product for sale or distribution in the United States.

[(21)] (22) TOBACCO WAREHOUSE.—

(A) Subject to subparagraphs (B) and (C), the term “tobacco warehouse” includes any person—

(i) who—

(I) removes foreign material from tobacco leaf through nothing other than a mechanical process;

(II) humidifies tobacco leaf with nothing other than potable water in the form of steam or mist;

or

(III) de-stems, dries, and packs tobacco leaf for storage and shipment;

(ii) who performs no other actions with respect to tobacco leaf; and

(iii) who provides to any manufacturer to whom the person sells tobacco all information related to the person’s actions described in clause (i) that is necessary for compliance with this Act.

(B) The term “tobacco warehouse” excludes any person who—

(i) reconstitutes tobacco leaf;

(ii) is a manufacturer, distributor, or retailer of a tobacco product; or

(iii) applies any chemical, additive, or substance to the tobacco leaf other than potable water in the form of steam or mist.

(C) The definition of the term “tobacco warehouse” in subparagraph (A) shall not apply to the extent to which the Secretary determines, through rulemaking, that regulation under this chapter of the actions described in such

subparagraph is appropriate for the protection of the public health.

[(22)] (23) UNITED STATES.—The term “United States” means the 50 States of the United States of America and the District of Columbia, the Commonwealth of Puerto Rico, Guam, the Virgin Islands, American Samoa, Wake Island, Midway Islands, Kingman Reef, Johnston Atoll, the Northern Mariana Islands, and any other trust territory or possession of the United States.

SEC. 901. FDA AUTHORITY OVER TOBACCO PRODUCTS.

(a) IN GENERAL.—Tobacco products, including modified risk tobacco products for which an order has been issued in accordance with section 911, shall be regulated by the Secretary under this chapter and shall not be subject to the provisions of chapter V.

[(b) APPLICABILITY.—This chapter shall apply to all cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco and to any other tobacco products that the Secretary by regulation deems to be subject to this chapter.]

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

(c) SCOPE.—

(1) IN GENERAL.—Nothing in this chapter, or any policy issued or regulation promulgated thereunder, or in sections 101(a), 102, or 103 of title I, title II, or title III of the Family Smoking Prevention and Tobacco Control Act, shall be construed to affect, expand, or limit the Secretary’s authority over (including the authority to determine whether products may be regulated), or the regulation of, products under this Act that are not tobacco products under chapter V or any other chapter.

(2) LIMITATION OF AUTHORITY.—

(A) IN GENERAL.—The provisions of this chapter shall not apply to tobacco leaf that is not in the possession of a manufacturer of tobacco products, or to the producers of tobacco leaf, including tobacco growers, tobacco warehouses, and tobacco grower cooperatives, nor shall any employee of the Food and Drug Administration have any authority to enter onto a farm owned by a producer of tobacco leaf without the written consent of such producer.

(B) EXCEPTION.—Notwithstanding subparagraph (A), if a producer of tobacco leaf is also a tobacco product manufacturer or controlled by a tobacco product manufacturer, the producer shall be subject to this chapter in the producer’s capacity as a manufacturer. The exception in this subparagraph shall not apply to a producer of tobacco leaf who grows tobacco under a contract with a tobacco product manufacturer and who is not otherwise engaged in the manufacturing process.

(C) RULE OF CONSTRUCTION.—Nothing in this chapter shall be construed to grant the Secretary authority to promulgate regulations on any matter that involves the production of tobacco leaf or a producer thereof, other than activities by a manufacturer affecting production.

(d) RULEMAKING PROCEDURES.—Each rulemaking under this chapter shall be in accordance with chapter 5 of title 5, United States Code. This subsection shall not be construed to affect the

rulemaking provisions of section 102(a) of the Family Smoking Prevention and Tobacco Control Act.

(e) **CENTER FOR TOBACCO PRODUCTS.**—Not later than 90 days after the date of enactment of the Family Smoking Prevention and Tobacco Control Act, the Secretary shall establish within the Food and Drug Administration the Center for Tobacco Products, which shall report to the Commissioner of Food and Drugs in the same manner as the other agency centers within the Food and Drug Administration. The Center shall be responsible for the implementation of this chapter and related matters assigned by the Commissioner.

(f) **OFFICE TO ASSIST SMALL TOBACCO PRODUCT MANUFACTURERS.**—The Secretary shall establish within the Food and Drug Administration an identifiable office to provide technical and other nonfinancial assistance to small tobacco product manufacturers to assist them in complying with the requirements of this Act.

(g) **CONSULTATION PRIOR TO RULEMAKING.**—Prior to promulgating rules under this chapter, the Secretary shall endeavor to consult with other Federal agencies as appropriate.

* * * * *

SEC. 906. GENERAL PROVISIONS RESPECTING CONTROL OF TOBACCO PRODUCTS.

(a) **IN GENERAL.**—Any requirement established by or under section 902, 903, 905, or 909 applicable to a tobacco product shall apply to such tobacco product until the applicability of the requirement to the tobacco product has been changed by action taken under section 907, section 910, section 911, or subsection (d) of this section, and any requirement established by or under section 902, 903, 905, or 909 which is inconsistent with a requirement imposed on such tobacco product under section 907, section 910, section 911, or subsection (d) of this section shall not apply to such tobacco product.

(b) **INFORMATION ON PUBLIC ACCESS AND COMMENT.**—Each notice of proposed rulemaking or other notification under section 907, 908, 909, 910, or 911 or under this section, any other notice which is published in the Federal Register with respect to any other action taken under any such section and which states the reasons for such action, and each publication of findings required to be made in connection with rulemaking under any such section shall set forth—

(1) the manner in which interested persons may examine data and other information on which the notice or findings is based; and

(2) the period within which interested persons may present their comments on the notice or findings (including the need therefore) orally or in writing, which period shall be at least 60 days but may not exceed 90 days unless the time is extended by the Secretary by a notice published in the Federal Register stating good cause therefore.

(c) **LIMITED CONFIDENTIALITY OF INFORMATION.**—Any information reported to or otherwise obtained by the Secretary or the Secretary's representative under section 903, 904, 907, 908, 909, 910, 911, or 704, or under subsection (e) or (f) of this section, which is exempt from disclosure under subsection (a) of section 552 of title

5, United States Code, by reason of subsection (b)(4) of that section shall be considered confidential and shall not be disclosed, except that the information may be disclosed to other officers or employees concerned with carrying out this chapter, or when relevant in any proceeding under this chapter.

(d) RESTRICTIONS.—

(1) IN GENERAL.—The Secretary may by regulation require restrictions on the sale and distribution of a tobacco product, including restrictions on the access to, and the advertising and promotion of, the tobacco product, if the Secretary determines that such regulation would be appropriate for the protection of the public health. The Secretary may by regulation impose restrictions on the advertising and promotion of a tobacco product consistent with and to full extent permitted by the first amendment to the Constitution. The finding as to whether such regulation would be appropriate for the protection of the public health shall be determined with respect to the risks and benefits to the population as a whole, including users and nonusers of the tobacco product, and taking into account—

(A) the increased or decreased likelihood that existing users of tobacco products will stop using such products; and

(B) the increased or decreased likelihood that those who do not use tobacco products will start using such products. No such regulation may require that the sale or distribution of a tobacco product be limited to the written or oral authorization of a practitioner licensed by law to prescribe medical products.

(2) LABEL STATEMENTS.—The label of a tobacco product shall bear such appropriate statements of the restrictions required by a regulation under subsection (a) as the Secretary may in such regulation prescribe.

[(3) LIMITATIONS.—

[(A) IN GENERAL.—No restrictions under paragraph (1) may—

[(i) prohibit the sale of any tobacco product in face-to-face transactions by a specific category of retail outlets; or

[(ii) establish a minimum age of sale of tobacco products to any person older than 18 years of age.

[(B) MATCHBOOKS.—For purposes of any regulations issued by the Secretary, matchbooks of conventional size containing not more than 20 paper matches, and which are customarily given away for free with the purchase of tobacco products, shall be considered as adult-written publications which shall be permitted to contain advertising. Notwithstanding the preceding sentence, if the Secretary finds that such treatment of matchbooks is not appropriate for the protection of the public health, the Secretary may determine by regulation that matchbooks shall not be considered adult-written publications.

[(4) REMOTE SALES.—

[(A) IN GENERAL.—The Secretary shall—

[(i) within 18 months after the date of enactment of the Family Smoking Prevention and Tobacco Control

Act, promulgate regulations regarding the sale and distribution of tobacco products 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 to individuals who have not attained the minimum age established by applicable law for the purchase of such products, including requirements for age verification; and

[(ii) within 2 years after such date of enactment, issue regulations to address the promotion and marketing of tobacco products that are sold or distributed through means other than a direct, face-to-face exchange between a retailer and a consumer in order to protect individuals who have not attained the minimum age established by applicable law for the purchase of such products.

[(B) RELATION TO OTHER AUTHORITY.—Nothing in this paragraph limits the authority of the Secretary to take additional actions under the other paragraphs of this subsection.]

(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).*

(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).*

(e) *GOOD MANUFACTURING PRACTICE REQUIREMENTS.*—

(1) *METHODS, FACILITIES, AND CONTROLS TO CONFORM.*—

(A) *IN GENERAL.*—*In applying manufacturing restrictions to tobacco, the Secretary shall, in accordance with subparagraph (B), prescribe regulations (which may differ based on the type of tobacco product involved) requiring that the methods used in, and the facilities and controls used for, the manufacture, preproduction design validation (including a process to assess the performance of a tobacco product), packing, and storage of a tobacco product conform to current good manufacturing practice, or hazard analysis and critical control point methodology, as prescribed in such regulations to assure that the public health is protected and that the tobacco product is in compliance with this chapter. Such regulations may provide for the testing of raw tobacco for pesticide chemical residues regardless of whether a tolerance for such chemical residues has been established.*

(B) *REQUIREMENTS.*—*The Secretary shall—*

(i) *before promulgating any regulation under subparagraph (A), afford the Tobacco Products Scientific Advisory Committee an opportunity to submit recommendations with respect to the regulation proposed to be promulgated;*

(ii) *before promulgating any regulation under subparagraph (A), afford opportunity for an oral hearing;*

(iii) *provide the Tobacco Products Scientific Advisory Committee a reasonable time to make its rec-*

ommendation with respect to proposed regulations under subparagraph (A);

(iv) in establishing the effective date of a regulation promulgated under this subsection, take into account the differences in the manner in which the different types of tobacco products have historically been produced, the financial resources of the different tobacco product manufacturers, and the state of their existing manufacturing facilities, and shall provide for a reasonable period of time for such manufacturers to conform to good manufacturing practices; and

(v) not require any small tobacco product manufacturer to comply with a regulation under subparagraph (A) for at least 4 years following the effective date established by the Secretary for such regulation.

(2) EXEMPTIONS; VARIANCES.—

(A) PETITION.—Any person subject to any requirement prescribed under paragraph (1) may petition the Secretary for a permanent or temporary exemption or variance from such requirement. Such a petition shall be submitted to the Secretary in such form and manner as the Secretary shall prescribe and shall—

(i) in the case of a petition for an exemption from a requirement, set forth the basis for the petitioner's determination that compliance with the requirement is not required to assure that the tobacco product will be in compliance with this chapter;

(ii) in the case of a petition for a variance from a requirement, set forth the methods proposed to be used in, and the facilities and controls proposed to be used for, the manufacture, packing, and storage of the tobacco product in lieu of the methods, facilities, and controls prescribed by the requirement; and

(iii) contain such other information as the Secretary shall prescribe.

(B) REFERRAL TO THE TOBACCO PRODUCTS SCIENTIFIC ADVISORY COMMITTEE.—The Secretary may refer to the Tobacco Products Scientific Advisory Committee any petition submitted under subparagraph (A). The Tobacco Products Scientific Advisory Committee shall report its recommendations to the Secretary with respect to a petition referred to it within 60 days after the date of the petition's referral. Within 60 days after—

(i) the date the petition was submitted to the Secretary under subparagraph (A); or

(ii) the day after the petition was referred to the Tobacco Products Scientific Advisory Committee, whichever occurs later, the Secretary shall by order either deny the petition or approve it.

(C) APPROVAL.—The Secretary may approve—

(i) a petition for an exemption for a tobacco product from a requirement if the Secretary determines that compliance with such requirement is not required to assure that the tobacco product will be in compliance with this chapter; and

(ii) a petition for a variance for a tobacco product from a requirement if the Secretary determines that the methods to be used in, and the facilities and controls to be used for, the manufacture, packing, and storage of the tobacco product in lieu of the methods, facilities, and controls prescribed by the requirement are sufficient to assure that the tobacco product will be in compliance with this chapter.

(D) CONDITIONS.—An order of the Secretary approving a petition for a variance shall prescribe such conditions respecting the methods used in, and the facilities and controls used for, the manufacture, packing, and storage of the tobacco product to be granted the variance under the petition as may be necessary to assure that the tobacco product will be in compliance with this chapter.

(E) HEARING.—After the issuance of an order under subparagraph (B) respecting a petition, the petitioner shall have an opportunity for an informal hearing on such order.

(3) COMPLIANCE.—Compliance with requirements under this subsection shall not be required before the end of the 3-year period following the date of enactment of the Family Smoking Prevention and Tobacco Control Act.

(f) RESEARCH AND DEVELOPMENT.—The Secretary may enter into contracts for research, testing, and demonstrations respecting tobacco products and may obtain tobacco products for research, testing, and demonstration purposes.

(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. 907. TOBACCO PRODUCT STANDARDS.

(a) IN GENERAL.—

(1) SPECIAL RULES.—

[(A) SPECIAL RULE FOR CIGARETTES.—Beginning 3 months after the date of enactment of the Family Smoking Prevention and Tobacco Control Act, a cigarette or any of its component parts (including the tobacco, filter, or paper) shall not contain, as a constituent (including a smoke constituent) or additive, an artificial or natural flavor (other than tobacco or menthol) or an herb or spice, including strawberry, grape, orange, clove, cinnamon, pineapple, vanilla, coconut, licorice, cocoa, chocolate, cherry, or coffee, that is a characterizing flavor of the tobacco product or tobacco smoke. 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 menthol or any artificial or natural flavor, herb, or spice not specified in this subparagraph.]

(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 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) *ADDITIONAL SPECIAL RULE.*—Beginning 2 years after the date of enactment of the Family Smoking Prevention and Tobacco Control Act, a tobacco product manufacturer shall not use tobacco, including foreign grown tobacco, that contains a pesticide chemical residue that is at a level greater than is specified by any tolerance applicable under Federal law to domestically grown tobacco.

(2) *REVISION OF TOBACCO PRODUCT STANDARDS.*—The Secretary may revise the tobacco product standards in paragraph (1) in accordance with subsection (c).

(3) *TOBACCO PRODUCT STANDARDS.*—

(A) *IN GENERAL.*—The Secretary may adopt tobacco product standards in addition to those in paragraph (1) if the Secretary finds that a tobacco product standard is appropriate for the protection of the public health.

(B) *DETERMINATIONS.*—

(i) *CONSIDERATIONS.*—In making a finding described in subparagraph (A), the Secretary shall consider scientific evidence concerning—

(I) the risks and benefits to the population as a whole, including users and nonusers of tobacco products, of the proposed standard;

(II) the increased or decreased likelihood that existing users of tobacco products will stop using such products; and

(III) the increased or decreased likelihood that those who do not use tobacco products will start using such products.

(ii) *ADDITIONAL CONSIDERATIONS.*—In the event that the Secretary makes a determination, set forth in a proposed tobacco product standard in a proposed rule, that it is appropriate for the protection of public health to require the reduction or elimination of an additive, constituent (including a smoke constituent), or other component of a tobacco product because the Secretary has found that the additive, constituent, or other component is or may be harmful, any party objecting to the proposed standard on the ground that the proposed standard will not reduce or eliminate the risk of illness or injury may provide for the Secretary's consideration scientific evidence that demonstrates that the proposed standard will not reduce or eliminate the risk of illness or injury.

(4) *CONTENT OF TOBACCO PRODUCT STANDARDS.*—A tobacco product standard established under this section for a tobacco product—

(A) shall include provisions that are appropriate for the protection of the public health, including provisions, where appropriate—

- (i) for nicotine yields of the product;
- (ii) for the reduction or elimination of other constituents, including smoke constituents, or harmful components of the product; or
- (iii) relating to any other requirement under subparagraph (B);

(B) shall, where appropriate for the protection of the public health, include—

- (i) provisions respecting the construction, components, ingredients, additives, constituents, including smoke constituents, and properties of the tobacco product;
- (ii) provisions for the testing (on a sample basis or, if necessary, on an individual basis) of the tobacco product;
- (iii) provisions for the measurement of the tobacco product characteristics of the tobacco product;
- (iv) provisions requiring that the results of each or of certain of the tests of the tobacco product required to be made under clause (ii) show that the tobacco product is in conformity with the portions of the standard for which the test or tests were required; and
- (v) a provision requiring that the sale and distribution of the tobacco product be restricted but only to the extent that the sale and distribution of a tobacco product may be restricted under a regulation under section 906(d);

(C) shall, where appropriate, require the use and prescribe the form and content of labeling for the proper use of the tobacco product; and

(D) shall require tobacco products containing foreign-grown tobacco to meet the same standards applicable to tobacco products containing domestically grown tobacco.

(5) PERIODIC REEVALUATION OF TOBACCO PRODUCT STANDARDS.—The Secretary shall provide for periodic evaluation of tobacco product standards established under this section to determine whether such standards should be changed to reflect new medical, scientific, or other technological data. The Secretary may provide for testing under paragraph (4)(B) by any person.

(6) INVOLVEMENT OF OTHER AGENCIES; INFORMED PERSONS.—In carrying out duties under this section, the Secretary shall endeavor to—

- (A) use personnel, facilities, and other technical support available in other Federal agencies;
- (B) consult with other Federal agencies concerned with standard setting and other nationally or internationally recognized standard-setting entities; and
- (C) invite appropriate participation, through joint or other conferences, workshops, or other means, by informed persons representative of scientific, professional, industry,

agricultural, or consumer organizations who in the Secretary's judgment can make a significant contribution.

(b) CONSIDERATIONS BY SECRETARY.—

(1) TECHNICAL ACHIEVABILITY.—The Secretary shall consider information submitted in connection with a proposed standard regarding the technical achievability of compliance with such standard.

(2) OTHER CONSIDERATIONS.—The Secretary shall consider all other information submitted in connection with a proposed standard, including information concerning the countervailing effects of the tobacco product standard on the health of adolescent tobacco users, adult tobacco users, or nontobacco users, such as the creation of a significant demand for contraband or other tobacco products that do not meet the requirements of this chapter and the significance of such demand.

(c) PROPOSED STANDARDS.—

(1) IN GENERAL.—The Secretary shall publish in the Federal Register a notice of proposed rulemaking for the establishment, amendment, or revocation of any tobacco product standard.

(2) REQUIREMENTS OF NOTICE.—A notice of proposed rulemaking for the establishment or amendment of a tobacco product standard for a tobacco product shall—

(A) set forth a finding with supporting justification that the tobacco product standard is appropriate for the protection of the public health;

(B) invite interested persons to submit a draft or proposed tobacco product standard for consideration by the Secretary;

(C) invite interested persons to submit comments on structuring the standard so that it does not advantage foreign-grown tobacco over domestically grown tobacco; and

(D) invite the Secretary of Agriculture to provide any information or analysis which the Secretary of Agriculture believes is relevant to the proposed tobacco product standard.

(3) FINDING.—A notice of proposed rulemaking for the revocation of a tobacco product standard shall set forth a finding with supporting justification that the tobacco product standard is no longer appropriate for the protection of the public health.

(4) COMMENT.—The Secretary shall provide for a comment period of not less than 60 days.

(d) PROMULGATION.—

(1) IN GENERAL.—After the expiration of the period for comment on a notice of proposed rulemaking published under subsection (c) respecting a tobacco product standard and after consideration of comments submitted under subsections (b) and (c) and any report from the Tobacco Products Scientific Advisory Committee, the Secretary shall—

(A) if the Secretary determines that the standard would be appropriate for the protection of the public health, promulgate a regulation establishing a tobacco product standard and publish in the Federal Register findings on the matters referred to in subsection (c); or

(B) publish a notice terminating the proceeding for the development of the standard together with the reasons for such termination.

(2) EFFECTIVE DATE.—A regulation establishing a tobacco product standard shall set forth the date or dates upon which the standard shall take effect, but no such regulation may take effect before 1 year after the date of its publication unless the Secretary determines that an earlier effective date is necessary for the protection of the public health. Such date or dates shall be established so as to minimize, consistent with the public health, economic loss to, and disruption or dislocation of, domestic and international trade. In establishing such effective date or dates, the Secretary shall consider information submitted in connection with a proposed product standard by interested parties, including manufacturers and tobacco growers, regarding the technical achievability of compliance with the standard, and including information concerning the existence of patents that make it impossible to comply in the timeframe envisioned in the proposed standard. If the Secretary determines, based on the Secretary's evaluation of submitted comments, that a product standard can be met only by manufacturers requiring substantial changes to the methods of farming the domestically grown tobacco used by the manufacturer, the effective date of that product standard shall be not less than 2 years after the date of publication of the final regulation establishing the standard.

(3) LIMITATION ON POWER GRANTED TO THE FOOD AND DRUG ADMINISTRATION.—Because of the importance of a decision of the Secretary to issue a regulation—

(A) banning all cigarettes, all smokeless tobacco products, all little cigars, all cigars other than little cigars, all pipe tobacco, or all roll-your-own tobacco products; or

(B) requiring the reduction of nicotine yields of a tobacco product to zero,

the Secretary is prohibited from taking such actions under this Act.

(4) AMENDMENT; REVOCATION.—

(A) AUTHORITY.—The Secretary, upon the Secretary's own initiative or upon petition of an interested person, may by a regulation, promulgated in accordance with the requirements of subsection (c) and paragraph (2), amend or revoke a tobacco product standard.

(B) EFFECTIVE DATE.—The Secretary may declare a proposed amendment of a tobacco product standard to be effective on and after its publication in the Federal Register and until the effective date of any final action taken on such amendment if the Secretary determines that making it so effective is in the public interest.

(5) REFERRAL TO ADVISORY COMMITTEE.—

(A) IN GENERAL.—The Secretary may refer a proposed regulation for the establishment, amendment, or revocation of a tobacco product standard to the Tobacco Products Scientific Advisory Committee for a report and recommendation with respect to any matter involved in the

proposed regulation which requires the exercise of scientific judgment.

(B) INITIATION OF REFERRAL.—The Secretary may make a referral under this paragraph—

- (i) on the Secretary's own initiative; or
- (ii) upon the request of an interested person that—
 - (I) demonstrates good cause for the referral; and
 - (II) is made before the expiration of the period for submission of comments on the proposed regulation.

(C) PROVISION OF DATA.—If a proposed regulation is referred under this paragraph to the Tobacco Products Scientific Advisory Committee, the Secretary shall provide the Advisory Committee with the data and information on which such proposed regulation is based.

(D) REPORT AND RECOMMENDATION.—The Tobacco Products Scientific Advisory Committee shall, within 60 days after the referral of a proposed regulation under this paragraph and after independent study of the data and information furnished to it by the Secretary and other data and information before it, submit to the Secretary a report and recommendation respecting such regulation, together with all underlying data and information and a statement of the reason or basis for the recommendation.

(E) PUBLIC AVAILABILITY.—The Secretary shall make a copy of each report and recommendation under subparagraph (D) publicly available.

(e) MENTHOL CIGARETTES.—

(1) REFERRAL; CONSIDERATIONS.—Immediately upon the establishment of the Tobacco Products Scientific Advisory Committee under section 917(a), the Secretary shall refer to the Committee for report and recommendation, under section 917(c)(4), the issue of the impact of the use of menthol in cigarettes on the public health, including such use among children, African-Americans, Hispanics, and other racial and ethnic minorities. In its review, the Tobacco Products Scientific Advisory Committee shall address the considerations listed in subsections (a)(3)(B)(i) and (b).

(2) REPORT AND RECOMMENDATION.—Not later than 1 year after its establishment, the Tobacco Product Scientific Advisory Committee shall submit to the Secretary the report and recommendations required pursuant to paragraph (1).

(3) RULE OF CONSTRUCTION.—Nothing in this subsection shall be construed to limit the Secretary's authority to take action under this section or other sections of this Act applicable to menthol.

(f) DISSOLVABLE TOBACCO PRODUCTS.—

(1) REFERRAL; CONSIDERATIONS.—The Secretary shall refer to the Tobacco Products Scientific Advisory Committee for report and recommendation, under section 917(c)(4), the issue of the nature and impact of the use of dissolvable tobacco products on the public health, including such use among children. In its review, the Tobacco Products Scientific Advisory Committee shall address the considerations listed in subsection (a)(3)(B)(i).

(2) REPORT AND RECOMMENDATION.—Not later than 2 years after its establishment, the Tobacco Product Scientific Advisory Committee shall submit to the Secretary the report and recommendations required pursuant to paragraph (1).

(3) RULE OF CONSTRUCTION.—Nothing in this subsection shall be construed to limit the Secretary’s authority to take action under this section or other sections of this Act at any time applicable to any dissolvable tobacco product.

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SEC. 910. APPLICATION FOR REVIEW OF CERTAIN TOBACCO PRODUCTS.

(a) IN GENERAL.—

(1) NEW TOBACCO PRODUCT DEFINED.—For purposes of this section the term “new tobacco product” means—

(A) any tobacco product (including those products in test markets) that was not commercially marketed in the United States as of February 15, 2007; or

(B) any modification (including a change in design, any component, any part, or any constituent, including a smoke constituent, or in the content, delivery or form of nicotine, or any other additive or ingredient) of a tobacco product where the modified product was commercially marketed in the United States after February 15, 2007.

(2) PREMARKET REVIEW REQUIRED.—

(A) NEW PRODUCTS.—An order under subsection

(c)(1)(A)(i) for a new tobacco product is required unless—

(i) the manufacturer has submitted a report under section 905(j); and the Secretary has issued an order that the tobacco product—

(I) is substantially equivalent to a tobacco product commercially marketed (other than for test marketing) in the United States as of February 15, 2007; and

(II) is in compliance with the requirements of this Act; **[or]**

(ii) the tobacco product is exempt from the requirements of section 905(j) pursuant to a regulation issued under section 905(j)(3) **[.]**; or

(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.

(B) APPLICATION TO CERTAIN POST-FEBRUARY 15, 2007, PRODUCTS.—Subparagraph (A) shall not apply to a tobacco product—

(i) that was first introduced or delivered for introduction into interstate commerce for commercial distribution in the United States after February 15, 2007, and prior to the date that is 21 months after the date of enactment of the Family Smoking Prevention and Tobacco Control Act; and

(ii) for which a report was submitted under section 905(j) within such 21-month period,

except that subparagraph (A) shall apply to the tobacco product if the Secretary issues an order that the tobacco product is not substantially equivalent.

(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.

(3) SUBSTANTIALLY EQUIVALENT DEFINED.—

(A) IN GENERAL.—In this section and section 905(j), the term “substantially equivalent” or “substantial equivalence” means, with respect to the tobacco product being compared to the predicate tobacco product, that the Secretary by order has found that the tobacco product—

(i) has the same characteristics as the predicate tobacco product; or

(ii) has different characteristics and the information submitted contains information, including clinical data if deemed necessary by the Secretary, that demonstrates that it is not appropriate to regulate the product under this section because the product does not raise different questions of public health.

(B) CHARACTERISTICS.—In subparagraph (A), the term “characteristics” means the materials, ingredients, design, composition, heating source, or other features of a tobacco product.

(C) LIMITATION.—A tobacco product may not be found to be substantially equivalent to a predicate tobacco product that has been removed from the market at the initiative of the Secretary or that has been determined by a judicial order to be misbranded or adulterated.

(4) HEALTH INFORMATION.—

(A) SUMMARY.—As part of a submission under section 905(j) respecting a tobacco product, the person required to file a premarket notification under such section shall provide an adequate summary of any health information related to the tobacco product or state that such information will be made available upon request by any person.

(B) REQUIRED INFORMATION.—Any summary under subparagraph (A) respecting a tobacco product shall contain detailed information regarding data concerning adverse health effects and shall be made available to the public by the Secretary within 30 days of the issuance of a determination that such tobacco product is substantially equivalent to another tobacco product.

(b) APPLICATION.—

(1) CONTENTS.—An application under this section shall contain—

(A) full reports of all information, published or known to, or which should reasonably be known to, the applicant, concerning investigations which have been made to show the health risks of such tobacco product and whether such tobacco product presents less risk than other tobacco products;

(B) a full statement of the components, ingredients, additives, and properties, and of the principle or principles of operation, of such tobacco product;

(C) a full description of the methods used in, and the facilities and controls used for, the manufacture, processing,

and, when relevant, packing and installation of, such tobacco product;

(D) an identifying reference to any tobacco product standard under section 907 which would be applicable to any aspect of such tobacco product, and either adequate information to show that such aspect of such tobacco product fully meets such tobacco product standard or adequate information to justify any deviation from such standard;

(E) such samples of such tobacco product and of components thereof as the Secretary may reasonably require;

(F) specimens of the labeling proposed to be used for such tobacco product; and

(G) such other information relevant to the subject matter of the application as the Secretary may require.

(2) REFERRAL TO TOBACCO PRODUCTS SCIENTIFIC ADVISORY COMMITTEE.—Upon receipt of an application meeting the requirements set forth in paragraph (1), the Secretary—

(A) may, on the Secretary's own initiative; or

(B) may, upon the request of an applicant,

refer such application to the Tobacco Products Scientific Advisory Committee for reference and for submission (within such period as the Secretary may establish) of a report and recommendation respecting the application, together with all underlying data and the reasons or basis for the recommendation.

(c) ACTION ON APPLICATION.—

(1) DEADLINE.—

(A) IN GENERAL.—As promptly as possible, but in no event later than 180 days after the receipt of an application under subsection (b), the Secretary, after considering the report and recommendation submitted under subsection (b)(2), shall—

(i) issue an order that the new product may be introduced or delivered for introduction into interstate commerce if the Secretary finds that none of the grounds specified in paragraph (2) of this subsection applies; or

(ii) issue an order that the new product may not be introduced or delivered for introduction into interstate commerce if the Secretary finds (and sets forth the basis for such finding as part of or accompanying such denial) that 1 or more grounds for denial specified in paragraph (2) of this subsection apply.

(B) RESTRICTIONS ON SALE AND DISTRIBUTION.—An order under subparagraph (A)(i) may require that the sale and distribution of the tobacco product be restricted but only to the extent that the sale and distribution of a tobacco product may be restricted under a regulation under section 906(d).

(2) DENIAL OF APPLICATION.—The Secretary shall deny an application submitted under subsection (b) if, upon the basis of the information submitted to the Secretary as part of the application and any other information before the Secretary with respect to such tobacco product, the Secretary finds that—

(A) there is a lack of a showing that permitting such tobacco product to be marketed would be appropriate for the protection of the public health;

(B) the methods used in, or the facilities or controls used for, the manufacture, processing, or packing of such tobacco product do not conform to the requirements of section 906(e);

(C) based on a fair evaluation of all material facts, the proposed labeling is false or misleading in any particular; or

(D) such tobacco product is not shown to conform in all respects to a tobacco product standard in effect under section 907, and there is a lack of adequate information to justify the deviation from such standard.

(3) DENIAL INFORMATION.—Any denial of an application shall, insofar as the Secretary determines to be practicable, be accompanied by a statement informing the applicant of the measures required to remove such application from deniable form (which measures may include further research by the applicant in accordance with 1 or more protocols prescribed by the Secretary).

(4) BASIS FOR FINDING.—For purposes of this section, the finding as to whether the marketing of a tobacco product for which an application has been submitted is appropriate for the protection of the public health shall be determined with respect to the risks and benefits to the population as a whole, including users and nonusers of the tobacco product, and taking into account—

(A) the increased or decreased likelihood that existing users of tobacco products will stop using such products; and

(B) the increased or decreased likelihood that those who do not use tobacco products will start using such products.

(5) BASIS FOR ACTION.—

(A) INVESTIGATIONS.—For purposes of paragraph (2)(A), whether permitting a tobacco product to be marketed would be appropriate for the protection of the public health shall, when appropriate, be determined on the basis of well-controlled investigations, which may include 1 or more clinical investigations by experts qualified by training and experience to evaluate the tobacco product.

(B) OTHER EVIDENCE.—If the Secretary determines that there exists valid scientific evidence (other than evidence derived from investigations described in subparagraph (A)) which is sufficient to evaluate the tobacco product, the Secretary may authorize that the determination for purposes of paragraph (2)(A) be made on the basis of such evidence.

(d) WITHDRAWAL AND TEMPORARY SUSPENSION.—

(1) IN GENERAL.—The Secretary shall, upon obtaining, where appropriate, advice on scientific matters from the Tobacco Products Scientific Advisory Committee, and after due notice and opportunity for informal hearing for a tobacco product for which an order was issued under subsection (c)(1)(A)(i), issue an order withdrawing the order if the Secretary finds—

(A) that the continued marketing of such tobacco product no longer is appropriate for the protection of the public health;

(B) that the application contained or was accompanied by an untrue statement of a material fact;

(C) that the applicant—

(i) has failed to establish a system for maintaining records, or has repeatedly or deliberately failed to maintain records or to make reports, required by an applicable regulation under section 909;

(ii) has refused to permit access to, or copying or verification of, such records as required by section 704; or

(iii) has not complied with the requirements of section 905;

(D) on the basis of new information before the Secretary with respect to such tobacco product, evaluated together with the evidence before the Secretary when the application was reviewed, that the methods used in, or the facilities and controls used for, the manufacture, processing, packing, or installation of such tobacco product do not conform with the requirements of section 906(e) and were not brought into conformity with such requirements within a reasonable time after receipt of written notice from the Secretary of nonconformity;

(E) on the basis of new information before the Secretary, evaluated together with the evidence before the Secretary when the application was reviewed, that the labeling of such tobacco product, based on a fair evaluation of all material facts, is false or misleading in any particular and was not corrected within a reasonable time after receipt of written notice from the Secretary of such fact; or

(F) on the basis of new information before the Secretary, evaluated together with the evidence before the Secretary when such order was issued, that such tobacco product is not shown to conform in all respects to a tobacco product standard which is in effect under section 907, compliance with which was a condition to the issuance of an order relating to the application, and that there is a lack of adequate information to justify the deviation from such standard.

(2) APPEAL.—The holder of an application subject to an order issued under paragraph (1) withdrawing an order issued pursuant to subsection (c)(1)(A)(i) may, by petition filed on or before the 30th day after the date upon which such holder receives notice of such withdrawal, obtain review thereof in accordance with section 912.

(3) TEMPORARY SUSPENSION.—If, after providing an opportunity for an informal hearing, the Secretary determines there is reasonable probability that the continuation of distribution of a tobacco product under an order would cause serious, adverse health consequences or death, that is greater than ordinarily caused by tobacco products on the market, the Secretary shall by order temporarily suspend the authority of the manufacturer to market the product. If the Secretary issues such an order, the Secretary shall proceed expeditiously under paragraph (1) to withdraw such application.

(e) SERVICE OF ORDER.—An order issued by the Secretary under this section shall be served—

(1) in person by any officer or employee of the department designated by the Secretary; or

(2) by mailing the order by registered mail or certified mail addressed to the applicant at the applicant's last known address in the records of the Secretary.

(f) RECORDS.—

(1) ADDITIONAL INFORMATION.—In the case of any tobacco product for which an order issued pursuant to subsection (c)(1)(A)(i) for an application filed under subsection (b) is in effect, the applicant shall establish and maintain such records, and make such reports to the Secretary, as the Secretary may by regulation, or by order with respect to such application, prescribe on the basis of a finding that such records and reports are necessary in order to enable the Secretary to determine, or facilitate a determination of, whether there is or may be grounds for withdrawing or temporarily suspending such order.

(2) ACCESS TO RECORDS.—Each person required under this section to maintain records, and each person in charge of custody thereof, shall, upon request of an officer or employee designated by the Secretary, permit such officer or employee at all reasonable times to have access to and copy and verify such records.

(g) INVESTIGATIONAL TOBACCO PRODUCT EXEMPTION FOR INVESTIGATIONAL USE.—The Secretary may exempt tobacco products intended for investigational use from the provisions of this chapter under such conditions as the Secretary may by regulation prescribe.

(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.

* * * * *

SEC. 919. USER FEES.

(a) **ESTABLISHMENT OF QUARTERLY FEE.**—Beginning on the date of enactment of the Family Smoking Prevention and Tobacco Control Act, the Secretary shall in accordance with this section assess user fees on, and collect such fees from, each manufacturer and importer of tobacco products subject to this chapter. The fees shall be assessed and collected with respect to each quarter of each fiscal year, and the total amount assessed and collected for a fiscal year shall be the amount specified in subsection (b)(1) for such year, subject to subsection (c).

(b) **ASSESSMENT OF USER FEE.**—

(1) **AMOUNT OF ASSESSMENT.**—The total amount of user fees authorized to be assessed and collected under subsection (a) for a fiscal year is the following, as applicable to the fiscal year involved:

(A) For fiscal year 2009, \$85,000,000 (subject to subsection (e)).

(B) For fiscal year 2010, \$235,000,000.

(C) For fiscal year 2011, \$450,000,000.

(D) For fiscal year 2012, \$477,000,000.

(E) For fiscal year 2013, \$505,000,000.

(F) For fiscal year 2014, \$534,000,000.

(G) For fiscal year 2015, \$566,000,000.

(H) For fiscal year 2016, \$599,000,000.

(I) For fiscal year 2017, \$635,000,000.

(J) For fiscal year 2018, \$672,000,000.

[(K) For fiscal year 2019 and each subsequent fiscal year, \$712,000,000.]

(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.

(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 with respect to each class of tobacco products shall be an amount that is equal to the applicable percentage of each class for the fis-

cal year multiplied by the amount specified in paragraph (1) for the fiscal year.】

(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 calculated 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).

(B) *APPLICABLE PERCENTAGE.*—

(i) *IN GENERAL.*—For purposes of subparagraph (A), the applicable percentage for a fiscal year for each of the following classes of tobacco products shall be determined in accordance with clause (ii):

(I) Cigarettes.

(II) Cigars, including small cigars and cigars other than small cigars.

(III) Snuff.

(IV) Chewing tobacco.

(V) Pipe tobacco.

(VI) Roll-your-own tobacco.

(ii) *ALLOCATIONS.*—The applicable percentage of each class of tobacco product described in clause (i) for a fiscal year shall be the percentage determined under

section 625(c) of Public Law 108–357 for each such class of product for such fiscal year.

(iii) REQUIREMENT OF REGULATIONS.—Notwithstanding clause (ii), no user fees shall be assessed on a class of tobacco products unless such class of tobacco products is listed in section 901(b) or is deemed by the Secretary in a regulation under section 901(b) to be subject to this chapter.

(iv) REALLOCATIONS.—In the case of a class of tobacco products that is not listed in section 901(b) or deemed by the Secretary in a regulation under section 901(b) to be subject to this chapter, the amount of user fees that would otherwise be assessed to such class of tobacco products shall be reallocated to the classes of tobacco products that are subject to this chapter in the same manner and based on the same relative percentages otherwise determined under clause (ii).

(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 domestic 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 January 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) DETERMINATION OF USER FEE BY COMPANY.—

(A) IN GENERAL.—The total user fee to be paid by each manufacturer or importer of a particular class of tobacco products shall be determined for each quarter by multiplying—

- (i) such manufacturer’s or importer’s percentage share as determined under paragraph (4); by
- (ii) the portion of the user fee amount for the current quarter to be assessed on all manufacturers and importers of such class of tobacco products as determined under paragraph (2).

(B) NO FEE IN EXCESS OF PERCENTAGE SHARE.—No manufacturer or importer of tobacco products shall be required to pay a user fee in excess of the percentage share of such manufacturer or importer.

(4) ALLOCATION OF ASSESSMENT WITHIN EACH CLASS OF TOBACCO PRODUCT.—The percentage share of each manufacturer or importer of a particular class of tobacco products of the total user fee to be paid by all manufacturers or importers of that class of tobacco products [shall be the percentage determined for purposes of allocations under subsections (e) through (h) of section 625 of Public Law 108–357] shall be the percentage determined by the Secretary.

[(5) ALLOCATION FOR CIGARS.—Notwithstanding paragraph (4), if a user fee assessment is imposed on cigars, the percentage share of each manufacturer or importer of cigars shall be based on the excise taxes paid by such manufacturer or importer during the prior fiscal year.]

[(6)] (5) TIMING OF ASSESSMENT.—The Secretary shall notify each manufacturer and importer of tobacco products subject to this section of the amount of the quarterly assessment imposed on such manufacturer or importer under this subsection for each quarter of each fiscal year. Such notifications shall occur not later than 30 days prior to the end of the quarter for which such assessment is made, and payments of all assessments shall be made by the last day of the quarter involved.

[(7) MEMORANDUM OF UNDERSTANDING.—

[(A) IN GENERAL.—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 the information described in paragraphs (2)(B)(ii) and (4) and 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) ASSURANCES.—Beginning not later than fiscal year 2015, and for each subsequent fiscal year, the Secretary shall ensure that the Food and Drug Administration is able to determine the applicable percentages described in paragraph (2) and the percentage shares described in paragraph (4). The Secretary may carry out this subparagraph by entering into a contract with the head of the Federal agency referred to in subparagraph (A) to continue to provide the necessary information.]

(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.*

(c) CREDITING AND AVAILABILITY OF FEES.—

(1) IN GENERAL.—Fees authorized under subsection (a) shall be collected and available for obligation only to the extent and in the amount provided in advance in appropriations Acts, subject to paragraph (2)(D). Such fees are authorized to remain available until expended. Such sums as may be necessary may be transferred from the Food and Drug Administration salaries and expenses appropriation account without fiscal year limitation to such appropriation account for salaries and expenses with such fiscal year limitation.

(2) AVAILABILITY.—

(A) IN GENERAL.—Fees appropriated under paragraph (3) are available only for the purpose of paying the costs of the activities of the Food and Drug Administration related to the regulation of tobacco products under this chapter and the Family Smoking Prevention and Tobacco Control Act (referred to in this subsection as “tobacco regulation activities”), except that such fees may be used for the reimbursement specified in subparagraph (C).

(B) PROHIBITION AGAINST USE OF OTHER FUNDS.—

(i) IN GENERAL.—Except as provided in clause (ii), fees collected under subsection (a) are the only funds authorized to be made available for tobacco regulation activities.

(ii) STARTUP COSTS.—Clause (i) does not apply until October 1, 2009. Until such date, any amounts available to the Food and Drug Administration (excluding user fees) shall be available and allocated as needed to pay the costs of tobacco regulation activities.

(C) REIMBURSEMENT OF START-UP AMOUNTS.—

(i) IN GENERAL.—Any amounts allocated for the start-up period pursuant to subparagraph (B)(ii) shall be reimbursed through any appropriated fees collected under subsection (a), in such manner as the Secretary determines appropriate to ensure that such allocation results in no net change in the total amount of funds otherwise available, for the period from October 1, 2008, through September 30, 2010, for Food and Drug Administration programs and activities (other than tobacco regulation activities) for such period.

(ii) TREATMENT OF REIMBURSED AMOUNTS.—Amounts reimbursed under clause (i) shall be available for the programs and activities for which funds allocated for the start-up period were available, prior to such allocation, until September 30, 2010, notwithstanding any otherwise applicable limits on amounts for such programs or activities for a fiscal year.

(D) FEE COLLECTED DURING START-UP PERIOD.—Notwithstanding the first sentence of paragraph (1), fees under subsection (a) may be collected through September 30, 2009 under subparagraph (B)(ii) and shall be available for obligation and remain available until expended. Such offsetting collections shall be credited to the salaries and expenses account of the Food and Drug Administration.

(E) OBLIGATION OF START-UP COSTS IN ANTICIPATION OF AVAILABLE FEE COLLECTIONS.—Notwithstanding any other provision of law, following the enactment of an appropriation for fees under this section for fiscal year 2010, or any portion thereof, obligations for costs of tobacco regulation activities during the start-up period may be incurred in anticipation of the receipt of offsetting fee collections through procedures specified in section 1534 of title 31, United States Code.

(3) AUTHORIZATION OF APPROPRIATIONS.—For fiscal year 2009 and each subsequent fiscal year, there is authorized to be ap-

propriated for fees under this section an amount equal to the amount specified in subsection (b)(1) for the fiscal year.

(d) **COLLECTION OF UNPAID FEES.**—In any case where the Secretary does not receive payment of a fee assessed under subsection (a) within 30 days after it is due, such fee shall be treated as a claim of the United States Government subject to subchapter II of chapter 37 of title 31, United States Code.

(e) **APPLICABILITY TO FISCAL YEAR 2009.**—If the date of enactment of the Family Smoking Prevention and Tobacco Control Act occurs during fiscal year 2009, the following applies, subject to subsection (c):

(1) The Secretary shall determine the fees that would apply for a single quarter of such fiscal year according to the application of subsection (b) to the amount specified in paragraph (1)(A) of such subsection (referred to in this subsection as the “quarterly fee amounts”).

(2) For the quarter in which such date of enactment occurs, the amount of fees assessed shall be a pro rata amount, determined according to the number of days remaining in the quarter (including such date of enactment) and according to the daily equivalent of the quarterly fee amounts. Fees assessed under the preceding sentence shall not be collected until the next quarter.

(3) For the quarter following the quarter to which paragraph (2) applies, the full quarterly fee amounts shall be assessed and collected, in addition to collection of the pro rata fees assessed under paragraph (2).

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FAMILY SMOKING PREVENTION AND TOBACCO CONTROL ACT

DIVISION A—FAMILY SMOKING PRE- VENTION AND TOBACCO CONTROL ACT

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TITLE I—AUTHORITY OF THE FOOD AND DRUG ADMINISTRATION

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SEC. 103. CONFORMING AND OTHER AMENDMENTS TO GENERAL PRO- VISIONS.

(a) **AMENDMENT OF FEDERAL FOOD, DRUG, AND COSMETIC ACT.**—Except as otherwise expressly provided, whenever in this section an amendment is expressed in terms of an amendment to, or repeal of, a section or other provision, the reference is to a section or other provision of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.).

(b) **SECTION 301.**—Section 301 (21 U.S.C. 331) is amended—

- (1) in subsection (a), by inserting “tobacco product,” after “device,”;
- (2) in subsection (b), by inserting “tobacco product,” after “device,”;
- (3) in subsection (c), by inserting “tobacco product,” after “device,”;
- (4) in subsection (e)—
 - (A) by striking the period after “572(i)”; and
 - (B) by striking “or 761 or the refusal to permit access to” and inserting “761, 909, or 920 or the refusal to permit access to”;
- (5) in subsection (g), by inserting “tobacco product,” after “device,”;
- (6) in subsection (h), by inserting “tobacco product,” after “device,”;
- (7) in subsection (j)—
 - (A) by striking the period after “573”; and
 - (B) by striking “708, or 721” and inserting “708, 721, 904, 905, 906, 907, 908, 909, or 920(b)”;
- (8) in subsection (k), by inserting “tobacco product,” after “device,”;
- (9) by striking subsection (p) and inserting the following:

“(p) The failure to register in accordance with section 510 or 905, the failure to provide any information required by section 510(j), 510(k), 905(i), or 905(j), or the failure to provide a notice required by section 510(j)(2) or 905(i)(3).”;
- (10) by striking subsection (q)(1) and inserting the following:

“(q)(1) The failure or refusal—

 - “(A) to comply with any requirement prescribed under section 518, 520(g), 903(b), 907, 908, or 915;
 - “(B) to furnish any notification or other material or information required by or under section 519, 520(g), 904, 909, or 920; or
 - “(C) to comply with a requirement under section 522 or 913.”;
- (11) in subsection (q)(2), by striking “device,” and inserting “device or tobacco product,”;
- (12) in subsection (r), by inserting “or tobacco product” after the term “device” each time that such term appears; and
- (13) by adding at the end the following:

“(oo) The sale of tobacco products in violation of a no-tobacco-sale order issued under section 303(f).

“(pp) The introduction or delivery for introduction into interstate commerce of a tobacco product in violation of section 911.

“(qq)(1) Forging, counterfeiting, simulating, or falsely representing, or without proper authority using any mark, stamp (including tax stamp), tag, label, or other identification device upon any tobacco product or container or labeling thereof so as to render such tobacco product a counterfeit tobacco product.

“(2) Making, selling, disposing of, or keeping in possession, control, or custody, or concealing any punch, die, plate, stone, or other item that is designed to print, imprint, or reproduce the trademark, trade name, or other identifying mark, imprint, or device of another or any likeness of any of the foregoing upon any tobacco prod-

uct or container or labeling thereof so as to render such tobacco product a counterfeit tobacco product.

“(3) The doing of any act that causes a tobacco product to be a counterfeit tobacco product, or the sale or dispensing, or the holding for sale or dispensing, of a counterfeit tobacco product.

“(rr) The charitable distribution of tobacco products.

“(ss) The failure of a manufacturer or distributor to notify the Attorney General and the Secretary of the Treasury of their knowledge of tobacco products used in illicit trade.

“(tt) Making any express or implied statement or representation directed to consumers with respect to a tobacco product, in a label or labeling or through the media or advertising, that either conveys, or misleads or would mislead consumers into believing, that—

“(1) the product is approved by the Food and Drug Administration;

“(2) the Food and Drug Administration deems the product to be safe for use by consumers;

“(3) the product is endorsed by the Food and Drug Administration for use by consumers; or

“(4) the product is safe or less harmful by virtue of—

“(A) its regulation or inspection by the Food and Drug Administration; or

“(B) its compliance with regulatory requirements set by the Food and Drug Administration;

including any such statement or representation rendering the product misbranded under section 903.”.

(c) SECTION 303.—Section 303(f) (21 U.S.C. 333(f)) is amended—

(1) in paragraph (5)—

(A) by striking “paragraph (1), (2), (3), or (4)” each place such appears and inserting “paragraph (1), (2), (3), (4), or (9)”;.

(B) in subparagraph (A)—

(i) by striking “assessed” the first time it appears and inserting “assessed, or a no-tobacco-sale order may be imposed,”; and

(ii) by striking “penalty” the second time it appears and inserting “penalty, or upon whom a no-tobacco-sale order is to be imposed,”;

(C) in subparagraph (B)—

(i) by inserting after “penalty,” the following: “or the period to be covered by a no-tobacco-sale order,”; and

(ii) by adding at the end the following: “A no-tobacco-sale order permanently prohibiting an individual retail outlet from selling tobacco products shall include provisions that allow the outlet, after a specified period of time, to request that the Secretary compromise, modify, or terminate the order.”; and

(D) by adding at the end the following:

“(D) The Secretary may compromise, modify, or terminate, with or without conditions, any no-tobacco-sale order.”;

(2) in paragraph (6)—

(A) by inserting “or the imposition of a no-tobacco-sale order” after the term “penalty” each place such term appears; and

(B) by striking “issued.” and inserting “issued, or on which the no-tobacco-sale order was imposed, as the case may be.”; and

(3) by adding at the end the following:

“(8) If the Secretary finds that a person has committed repeated violations of restrictions promulgated under section 906(d) at a particular retail outlet then the Secretary may impose a no-tobacco-sale order on that person prohibiting the sale of tobacco products in that outlet. A no-tobacco-sale order may be imposed with a civil penalty under paragraph (1). Prior to the entry of a no-sale order under this paragraph, a person shall be entitled to a hearing pursuant to the procedures established through regulations of the Food and Drug Administration for assessing civil money penalties, including at a retailer’s request a hearing by telephone, or at the nearest regional or field office of the Food and Drug Administration, or at a Federal, State, or county facility within 100 miles from the location of the retail outlet, if such a facility is available.

“(9) CIVIL MONETARY PENALTIES FOR VIOLATION OF TOBACCO PRODUCT REQUIREMENTS.—

“(A) IN GENERAL.—Subject to subparagraph (B), any person who violates a requirement of this Act which relates to tobacco products shall be liable to the United States for a civil penalty in an amount not to exceed \$15,000 for each such violation, and not to exceed \$1,000,000 for all such violations adjudicated in a single proceeding.

“(B) ENHANCED PENALTIES.—

“(i) Any person who intentionally violates a requirement of section 902(5), 902(6), 904, 908(c), or 911(a), shall be subject to a civil monetary penalty of—

“(I) not to exceed \$250,000 per violation, and not to exceed \$1,000,000 for all such violations adjudicated in a single proceeding; or

“(II) in the case of a violation that continues after the Secretary provides written notice to such person, \$250,000 for the first 30-day period (or any portion thereof) that the person continues to be in violation, and such amount shall double for every 30-day period thereafter that the violation continues, not to exceed \$1,000,000 for any 30-day period, and not to exceed \$10,000,000 for all such violations adjudicated in a single proceeding.

“(ii) Any person who violates a requirement of section 911(g)(2)(C)(ii) or 911(i)(1), shall be subject to a civil monetary penalty of—

“(I) not to exceed \$250,000 per violation, and not to exceed \$1,000,000 for all such violations adjudicated in a single proceeding; or

“(II) in the case of a violation that continues after the Secretary provides written notice to such person, \$250,000 for the first 30-day period (or any portion thereof) that the person continues to be in violation, and such amount shall double for every 30-day period thereafter that the violation continues, not to exceed \$1,000,000 for any 30-day period, and not to exceed

\$10,000,000 for all such violations adjudicated in a single proceeding.

“(iii) In determining the amount of a civil penalty under clause (i)(II) or (ii)(II), the Secretary shall take into consideration whether the person is making efforts toward correcting the violation of the requirements of the section for which such person is subject to such civil penalty.”.

(d) SECTION 304.—Section 304 (21 U.S.C. 334) is amended—

(1) in subsection (a)(2)—

(A) by striking “and” before “(D)”; and

(B) by striking “device.” and inserting the following: “device, and (E) Any adulterated or misbranded tobacco product.”;

(2) in subsection (d)(1), by inserting “tobacco product,” after “device,”;

(3) in subsection (g)(1), by inserting “or tobacco product” after the term “device” each place such term appears; and

(4) in subsection (g)(2)(A), by inserting “or tobacco product” after “device”.

(e) SECTION 505.—Section 505(n)(2) (21 U.S.C. 355(n)(2)) is amended by striking “section 904” and inserting “section 1004”.

(f) SECTION 523.—Section 523(b)(2)(D) (21 U.S.C. 360m(b)(2)(D)) is amended by striking “section 903(g)” and inserting “section 1003(g)”.

(g) SECTION 702.—Section 702(a)(1) (U.S.C. 372(a)(1)) is amended—

(1) by striking “(a)(1)” and inserting “(a)(1)(A)”; and

(2) by adding at the end the following:

“(B)(i) For a tobacco product, to the extent feasible, the Secretary shall contract with the States in accordance with this paragraph to carry out inspections of retailers within that State in connection with the enforcement of this Act.

“(ii) The Secretary shall not enter into any contract under clause (i) with the government of any of the several States to exercise enforcement authority under this Act on Indian country without the express written consent of the Indian tribe involved.”.

(h) SECTION 703.—Section 703 (21 U.S.C. 373) is amended—

(1) by inserting “tobacco product,” after the term “device,” each place such term appears; and

(2) by inserting “tobacco products,” after the term “devices,” each place such term appears.

(i) SECTION 704.—Section 704 (21 U.S.C. 374) is amended—

(1) in subsection (a)(1)—

(A) by striking “devices, or cosmetics” each place it appears and inserting “devices, tobacco products, or cosmetics”;

(B) by striking “or restricted devices” each place it appears and inserting “restricted devices, or tobacco products”; and

(C) by striking “and devices and subject to” and all that follows through “other drugs or devices” and inserting “devices, and tobacco products and subject to reporting and inspection under regulations lawfully issued pursuant to section 505 (i) or (k), section 519, section 520(g), or chapter

- IX and data relating to other drugs, devices, or tobacco products”;
- (2) in subsection (b), by inserting “tobacco product,” after “device,”; and
- (3) in subsection (g)(13), by striking “section 903(g)” and inserting “section 1003(g)”.
- (j) SECTION 705.—Section 705(b) (21 U.S.C. 375(b)) is amended by inserting “tobacco products,” after “devices,”.
- (k) SECTION 709.—Section 709 (21 U.S.C. 379a) is amended by inserting “tobacco product,” after “device,”.
- (l) SECTION 801.—Section 801 (21 U.S.C. 381) is amended—
- (1) in subsection (a)—
- (A) by inserting “tobacco products,” after the term “devices,”;
- (B) by inserting “or section 905(h)” after “section 510”; and
- (C) by striking the term “drugs or devices” each time such term appears and inserting “drugs, devices, or tobacco products”;
- (2) in subsection (e)(1)—
- (A) by inserting “tobacco product” after “drug, device,”; and
- (B) by inserting “, and a tobacco product intended for export shall not be deemed to be in violation of section 906(e), 907, 911, or 920(a),” before “if it—”; and
- (3) by adding at the end the following:
- “(p)(1) Not later than 36 months after the date of enactment of the Family Smoking Prevention and Tobacco Control Act, and annually thereafter, the Secretary shall submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives, a report regarding—
- “(A) the nature, extent, and destination of United States tobacco product exports that do not conform to tobacco product standards established pursuant to this Act;
- “(B) the public health implications of such exports, including any evidence of a negative public health impact; and
- “(C) recommendations or assessments of policy alternatives available to Congress and the executive branch to reduce any negative public health impact caused by such exports.
- “(2) The Secretary is authorized to establish appropriate information disclosure requirements to carry out this subsection.”.
- (m) SECTION 1003.—Section 1003(d)(2)(C) (as redesignated by section 101(b)) is amended—
- (1) by striking “and” after “cosmetics,”; and
- (2) inserting “, and tobacco products” after “devices”.
- (n) SECTION 1009.—Section 1009(b) (as redesignated by section 101(b)) is amended by striking “section 908” and inserting “section 1008”.
- (o) SECTION 409 OF THE FEDERAL MEAT INSPECTION ACT.—Section 409(a) of the Federal Meat Inspection Act (21 U.S.C. 679(a)) is amended by striking “section 902(b)” and inserting “section 1002(b)”.
- (p) RULE OF CONSTRUCTION.—Nothing in this section is intended or shall be construed to expand, contract, or otherwise modify or

amend the existing limitations on State government authority over tribal restricted fee or trust lands.

(q) GUIDANCE AND EFFECTIVE DATES.—

(1) IN GENERAL.—The Secretary of Health and Human Services shall issue guidance—

(A) defining the term “repeated violation”, as used in section 303(f)(8) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 333(f)(8)) as amended by subsection (c), as including at least 5 violations of particular requirements over a 36-month period at a particular retail outlet that constitute a repeated violation and providing for civil penalties in accordance with paragraph (2);

(B) providing for timely and effective notice by certified or registered mail or personal delivery to the retailer of each alleged violation at a particular retail outlet prior to conducting a followup compliance check, such notice to be sent to the location specified on the retailer’s registration or to the retailer’s registered agent if the retailer has provided such agent information to the Food and Drug Administration prior to the violation;

(C) providing for a hearing pursuant to the procedures established through regulations of the Food and Drug Administration for assessing civil money penalties, including at a retailer’s request a hearing by telephone or at the nearest regional or field office of the Food and Drug Administration, and providing for an expedited procedure for the administrative appeal of an alleged violation;

(D) providing that a person may not be charged with a violation at a particular retail outlet unless the Secretary has provided notice to the retailer of all previous violations at that outlet;

(E) establishing that civil money penalties for multiple violations shall increase from one violation to the next violation pursuant to paragraph (2) within the time periods provided for in such paragraph;

(F) providing that good faith reliance on the presentation of a false government-issued photographic identification that contains a date of birth does not constitute a violation of any minimum age requirement for the sale of tobacco products if the retailer has taken effective steps to prevent such violations, including—

(i) adopting and enforcing a written policy against sales to minors;

(ii) informing its employees of all applicable laws;

(iii) establishing disciplinary sanctions for employee noncompliance; and

(iv) requiring its employees to verify age by way of photographic identification or electronic scanning device; and

(G) providing for the Secretary, in determining whether to impose a no-tobacco-sale order and in determining whether to compromise, modify, or terminate such an order, to consider whether the retailer has taken effective steps to prevent violations of the minimum age require-

ments for the sale of tobacco products, including the steps listed in subparagraph (F).

(2) PENALTIES FOR VIOLATIONS.—

[(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, \$0.00 together with the issuance of a warning letter to the retailer;

[(II) in the case of a second violation within a 12-month period, \$250;

[(III) in the case of a third violation within a 24-month period, \$500;

[(IV) in the case of a fourth violation within a 24-month period, \$2,000;

[(V) in the case of a fifth violation within a 36-month period, \$5,000; and

[(VI) in the case of a sixth or subsequent violation within a 48-month period, \$10,000 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, \$250;

[(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, \$2,000;

[(V) in the case of a fifth violation within a 36-month period, \$5,000; and

[(VI) in the case of a sixth or subsequent violation within a 48-month period, \$10,000 as determined by the Secretary on a case-by-case basis.]

(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) TRAINING PROGRAM.—For purposes of subparagraph (A), the term “approved training program” means a training program that complies with standards developed by the Food and Drug Administration for such programs.

(C) CONSIDERATION OF STATE PENALTIES.—The Secretary shall coordinate with the States in enforcing the provisions of this Act and, for purposes of mitigating a civil penalty to be applied for a violation by a retailer of any restriction promulgated under section 906(d), shall consider the amount of any penalties paid by the retailer to a State for the same violation.

(3) GENERAL EFFECTIVE DATE.—The amendments made by paragraphs (2), (3), and (4) of subsection (c) shall take effect upon the issuance of guidance described in paragraph (1) of this subsection.

(4) SPECIAL EFFECTIVE DATE.—The amendment made by subsection (c)(1) shall take effect on the date of enactment of this Act.

(5) PACKAGE LABEL REQUIREMENTS.—The package label requirements of paragraphs (3) and (4) of section 903(a) of the Federal Food, Drug, and Cosmetic Act (as amended by this division) shall take effect on the date that is 12 months after the date of enactment of this Act. The package label requirements of paragraph (2) of such section 903(a) for cigarettes shall take effect on the date that is 15 months after the issuance of the regulations required by section 4(d) of the Federal Cigarette Labeling and Advertising Act (15 U.S.C. 1333), as amended by section 201 of this division. The package label requirements of paragraph (2) of such section 903(a) for tobacco products other than cigarettes shall take effect on the date that is 12 months after the date of enactment of this Act. The effective date shall be with respect to the date of manufacture, provided that, in any case, beginning 30 days after such effective date, a manufacturer shall not introduce into the domestic commerce of the United States any product, irrespective of the date of manufac-

ture, that is not in conformance with section 903(a) (2), (3), and (4) and section 920(a) of the Federal Food, Drug, and Cosmetic Act.

(6) ADVERTISING REQUIREMENTS.—The advertising requirements of section 903(a)(8) of the Federal Food, Drug, and Cosmetic Act (as amended by this division) shall take effect on the date that is 12 months after the date of enactment of this Act.

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XVII. DISSENTING VIEWS

Reducing youth tobacco use is a shared goal of both Republicans and Democrats. A surge in the use of e-cigarettes has resulted in a dramatic increase in tobacco utilization by minors in recent years.¹ To combat this epidemic, Republicans put forth policy proposals such as “T21”—a federal prohibition on the sale and marketing of tobacco products to those under 21 years of age. The Administration also explored limiting the sale of electronic nicotine delivery systems (ENDS) to age restricted locations. Both policies aim to address the issue of “social sourcing”—when of-age high school students buy and resell tobacco products to their younger classmates. This is known to be a primary method through which minors have been acquiring ENDS products. We also supported passage of H.R. 3942, the Preventing Online Sales of E-Cigarettes to Children Act. This legislation requires age verification by retailers at the time of purchase, as well as identification at the point of delivery, and labeling clearly indicating that the package contains tobacco products. But H.R. 2339, the legislation considered before the Energy and Commerce Committee in November, goes well beyond the issue of youth vaping and takes aim at the entire tobacco industry, including products used legally by adults.

Flavored Tobacco Products

H.R. 2339 would ban all characterizing flavors for tobacco products and, with an exception for ENDS, would not provide any process for those products to return to the market.

Section 907(a)(1)(A) of the Federal Food, Drug, and Cosmetics Act (FFDCA) already prohibits the sale and marketing of cigarettes containing an artificial or natural flavor (other than menthol) that is a characterizing flavor of the tobacco product or tobacco smoke. H.R. 2339 would extend this prohibition to smokeless tobacco products, cigars, and pipe tobacco. These prohibitions amount to excessive government overreach and are unnecessary to achieve what is purported to be the intent of the legislation—to prevent youth tobacco use.

Data from the Centers for Disease Control and Prevention (CDC) demonstrates the use of these products by minors has been stagnant or declined in recent years. Between 2011–2019, the only type of tobacco product that contributed to a significant rise in youth tobacco utilization were ENDS products.² As such, a prohibition on all flavored tobacco products is unlikely to lead to substantial reductions in tobacco use by children. However, an across the board flavor ban for all tobacco products would result in fewer choices for adults who legally use them and could encourage consumers to

¹ <https://www.cdc.gov/media/releases/2019/p0211-youth-tobacco-use-increased.html>

² https://www.cdc.gov/tobacco/data_statistics/fact_sheets/youth_data/tobacco_use/index.htm

seek out illicit products in their absence. The belief that purchases will shift to the illicit market is not speculative—this marketplace already exists and is thriving. Illicit tobacco products already make up approximately 1 of every 10 tobacco products consumed globally, according to the World Health Organization (WHO).³ The risks of the illicit market are seen in the recently reported vaping illnesses and deaths that have been linked to products containing illicit THC. These products often contain dangerous substances, such as heavy metals and pesticides, posing increased risks to consumers. H.R. 2339 does nothing to combat the ongoing use of illicit products, despite many of these illegal THC products being marketed with kid-friendly flavors.

Several Republican members also have concerns about the legislation’s prohibition on menthol combustible cigarettes. The Food and Drug Administration (FDA) already has the authority to prohibit the sale and marketing of menthol cigarettes under section 907(a)(1)(A) and can do so if it determines such action is appropriate. These are decisions that should be made by the FDA based on sound science, not by Congress.

Finally, the legislation passed out of the Energy and Commerce Committee contains a product standard for flavored ENDS that differs from the current standard. While the legislation would not provide a path forward for the authorization of flavored traditional tobacco products, the current standard for all tobacco products is whether the product is “appropriate for the protection of the public health.” H.R. 2339 provides an exception to the ban that would allow flavored ENDS products to come to market, but it requires that a higher bar be met. In order to bring a flavored ENDS product to market, the manufacturer must demonstrate to the FDA that the use of flavor will increase the likelihood of smoking cessation, will not increase the likelihood that individuals who do not use tobacco will start, and is not more harmful than a non-flavored ENDS product. Republicans do not believe a new standard, imposed in statute, is needed for flavored products. Unless the science shows that a flavor, in and of itself, is unsafe or causes more harm to consumers, Congress should not force a science-based regulatory agency to treat it as such. Furthermore, FDA has the ability, under section 907(a)(3), to adopt additional product standards if the agency finds that such standard is “appropriate for the protection of the public health.” Therefore, if FDA determines that additional standards are needed to authorize flavored ENDS products, it can determine what the appropriate standard should be. Flavors themselves are not inherently dangerous and should not be treated as such. The implementation of this new standard in statute would make it unlikely that any ENDS products would ever be permitted to come to market, even if FDA determines authorization may be appropriate for the protection of the public health.

User Fees

The Center for Tobacco Products (CTP) is funded solely by the assessment and collection of user fees from tobacco product manufacturers and importers. Unlike other user fee programs within

³ <https://www.who.int/news-room/fact-sheets/detail/tobacco>

FDA, the tobacco user fee program is indefinite and does not require reauthorization.⁴ The tobacco product user fee program does require an annual appropriation from Congress, which provides FDA the authority to collect and spend fees. For Fiscal Year 2019 and subsequent years, the amount allowed to be assessed and collected by CTP is \$712 million. Section 919(b)(2)(B) specifies which tobacco product classes fees may be collected from: cigarettes, cigars, snuff, pipe tobacco, chewing tobacco, and roll-your-own tobacco. Since these product classes are dictated in statute, FDA has determined it does not have the statutory authority to collect fees from ENDS manufacturers or importers.⁵

H.R. 2339 aims to give FDA the authority to assess and collect user fees from tobacco products outside of the six product classes listed in statute. It also proposes increasing FDA's user fee authority to \$812 million for Fiscal Year 2020 and includes an inflation adjuster to determine the total amount of fees authorized to be collected from all tobacco product classes in subsequent years.

Republicans oppose providing FDA with an additional \$100 million in user fee authority, as well as allowing the fee amount to increase with inflation. The CTP is not subject to a user fee reauthorization, has avoided Congressional oversight, and has ignored statutorily required reporting mandates since its creation in the Tobacco Control Act ten years ago. Under section 106(a) of the Tobacco Control Act, FDA was required to submit a report three years after enactment, followed by biennial reports, on the implementation of the Act.⁶ To date, the only report that has been submitted to Congress is the 2012 report required three years after enactment, leaving three additional reports unaccounted for. The CTP has been able to function while avoiding Congressional oversight because the authorization for its user fee program, through which it receives all of its funding, does not sunset. All other FDA user fee programs are subject to periodic reauthorization by Congress, which encourages the agency to be transparent about how it uses the fees it collects. We do not believe the CTP should receive additional user fee dollars without more accountability and transparency to Congress.

Remote Retail Sales Ban

Some Republicans have also expressed concerns about the prohibition of remote retail sales for all tobacco products included in the legislation. While most tobacco products are sold in gas stations or convenience stores, this prohibition would be especially detrimental to the premium cigar industry given that most premium cigar products are sold to consumers online or through catalog purchases.

House Republicans have demonstrated a willingness to work with Democrats to address the increase in youth vaping through policies such as "T21." We have also shown an eagerness to investigate and act to stop use of illegal THC vape products that have resulted in thousands of illnesses across the country. However, we

⁴ <https://www.crs.gov/Reports/R45867?source=search&guid=5b14990f90be4d188b6d29fe71b1f8f8&index=0>

⁵ 21 CFR Part 1150

⁶ P.L. 11–31: "Family Smoking Prevention and Tobacco Control and Federal Retirement Reform Act of 2009."

cannot support a policy that results in vast government overreach and does not appropriately target the problems both sides wish to address.

GREG WALDEN,
*Republican Leader, Com-
mittee on Energy and
Commerce.*

MICHAEL C. BURGESS, M.D.,
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committee on Health,
Committee on Energy and
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