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116TH CONGRESS
2D SESSION

H. R. 2339

[Report No. 116–402]

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

IN THE HOUSE OF REPRESENTATIVES

APRIL 18, 2019

Mr. PALLONE (for himself and Ms. SHALALA) introduced the following bill;
which was referred to the Committee on Energy and Commerce

FEBRUARY 21, 2020

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

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

FEBRUARY 21, 2020

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

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

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

A BILL

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

1 *Be it enacted by the Senate and House of Representa-*
 2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 *This Act may be cited as the “Reversing the Youth To-*
 5 *bacco Epidemic Act of 2019”.*

6 **SEC. 2. TABLE OF CONTENTS.**

7 *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 ces-
sation 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

1 *Human Services, acting through the Commissioner of Food*
 2 *and Drugs, shall promulgate a final rule amending part*
 3 *1140 of subchapter K of title 21, Code of Federal Regula-*
 4 *tions—*

5 *(1) to apply the provisions of such part 1140 to*
 6 *all tobacco products, as applicable, to which chapter*
 7 *IX of the Federal Food, Drug, and Cosmetic Act (21*
 8 *U.S.C. 387a et seq.) applies pursuant to section*
 9 *901(b) of such Act (21 U.S.C. 387a(b)), as amended*
 10 *by section 103(a) of this Act; and*

11 *(2) to make such changes as may be necessary*
 12 *for consistency with the amendments made by section*
 13 *103 of this Act, including by updating all references*
 14 *to persons younger than 18 years of age in subpart*
 15 *B of part 1140 of title 21, Code of Federal Regula-*
 16 *tions.*

17 *(b) EFFECTIVE DATE.—The final rule required by sub-*
 18 *section (a) shall take effect on the date that is 2 years after*
 19 *the date of enactment of this Act.*

20 **SEC. 103. REDUCING CHILD AND ADOLESCENT NICOTINE**
 21 **ADDICTION.**

22 *(a) APPLICABILITY TO ALL TOBACCO PRODUCTS.—*

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

1 “(b) *APPLICABILITY.*—*This chapter shall apply to all*
 2 *tobacco products.*”.

3 (2) *RULE OF CONSTRUCTION.*—*Paragraph (1)*
 4 *and the amendment made thereby shall not be con-*
 5 *strued to limit the applicability of chapter IX of the*
 6 *Federal Food, Drug, and Cosmetic Act (21 U.S.C.*
 7 *387a et seq.) to—*

8 (A) *products that were listed in section*
 9 *901(b) of such Act as in effect on the day before*
 10 *the date of enactment of this Act; and*

11 (B) *products that were deemed by regula-*
 12 *tion to be subject to such chapter pursuant to*
 13 *section 901(b) of such Act as in effect on the day*
 14 *before the date of enactment of this Act.*

15 (b) *MINIMUM AGE RESTRICTIONS.*—

16 (1) *IN GENERAL.*—*Section 906(d) of the Federal*
 17 *Food, Drug, and Cosmetic Act (21 U.S.C. 387f(d)) is*
 18 *amended by striking paragraph (3) and inserting the*
 19 *following:*

20 “(3) *MINIMUM AGE RESTRICTIONS.*—

21 “(A) *RESTRICTION.*—*It shall be unlawful*
 22 *for any retailer, manufacturer, distributor,*
 23 *third-party marketplace, or any other commer-*
 24 *cial entity to sell a tobacco product to any per-*
 25 *son younger than 21 years of age.*

1 “(B) *AGE VERIFICATION.*—*To ensure com-*
2 *pliance with subparagraph (A), a retailer shall,*
3 *at a minimum, verify by means of a govern-*
4 *ment-issued photographic identification the age*
5 *of the individual purchasing the product as pre-*
6 *scribed in—*

7 “(i) *subpart B of part 1140 of sub-*
8 *chapter K of title 21, Code of Federal Regu-*
9 *lations; and*

10 “(ii) *successor regulations, including*
11 *the regulation required by section 102 of the*
12 *Reversing the Youth Tobacco Epidemic Act*
13 *of 2019 and any applicable regulation im-*
14 *posing restrictions pursuant to paragraph*
15 *(1).*

16 “(C) *REGULATIONS.*—*Not later than 180*
17 *days after the date of enactment of the Reversing*
18 *the Youth Tobacco Epidemic Act of 2019, the*
19 *Secretary shall promulgate a final regulation to*
20 *implement and enforce subparagraphs (A) and*
21 *(B).*

22 “(D) *TIMING.*—*Subparagraphs (A) and (B)*
23 *shall take effect on the date that is 180 days*
24 *after the date of enactment of the Reversing the*
25 *Youth Tobacco Epidemic Act of 2019, regardless*

1 *of whether the Secretary has promulgated the*
 2 *final regulations required by subparagraph*
 3 *(C).”.*

4 (2) *PRESERVATION OF STATE AND LOCAL AU-*
 5 *THORITY.—Nothing in the amendment made by para-*
 6 *graph (1) shall be construed to affect the preservation*
 7 *of State and local authority pursuant to section 916*
 8 *of the Federal Food, Drug, and Cosmetic Act (21*
 9 *U.S.C. 387p).*

10 (c) *PROHIBITING FLAVORING OF TOBACCO PROD-*
 11 *UCTS.—*

12 (1) *PROHIBITION.—*

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

17 “(A) *SPECIAL RULES.—*

18 “(i) *IN GENERAL.—Beginning on the*
 19 *date that is 1 year after the date of enact-*
 20 *ment of the Reversing the Youth Tobacco*
 21 *Epidemic Act of 2019, a tobacco product*
 22 *(including its components, parts, and acces-*
 23 *sories, including the tobacco, filter, or*
 24 *paper) that is not an electronic nicotine de-*
 25 *livery system shall not contain, as a con-*

1 *stituent (including a smoke constituent) or*
2 *additive, an artificial or natural flavor*
3 *(other than tobacco) that is a characterizing*
4 *flavor of the tobacco product or tobacco*
5 *smoke or an herb or spice, including men-*
6 *thol, mint, strawberry, grape, orange, clove,*
7 *cinnamon, pineapple, vanilla, coconut, lico-*
8 *rice, cocoa, chocolate, cherry, or coffee.*

9 “(ii) *RULE OF CONSTRUCTION.*—*Noth-*
10 *ing in this subparagraph shall be construed*
11 *to limit the Secretary’s authority to take ac-*
12 *tion under this section or other sections of*
13 *this Act applicable to any artificial or nat-*
14 *ural flavor, herb, or spice.*

15 “(iii) *APPLICABILITY TO CERTAIN IN-*
16 *DIVIDUALS.*—*Notwithstanding any provi-*
17 *sion of this Act, no individual who pur-*
18 *chases or possess for consumption a tobacco*
19 *product that is in violation of the prohibi-*
20 *tion under this subparagraph shall be sub-*
21 *ject to any criminal penalty under this Act*
22 *for such purchase or possession, nor shall it*
23 *be used as a justification to stop, search, or*
24 *conduct any other investigative measure*
25 *against any individual.”.*

1 (B) SAVINGS PROVISION.—Section 907(a)(1)
 2 of the Federal Food, Drug, and Cosmetic Act (21
 3 U.S.C. 387g(a)(1)), as in effect on the date of en-
 4 actment of this Act, shall remain in effect until
 5 the amendments made to such section 907(a)(1)
 6 by this paragraph take effect.

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

11 “(h) FLAVORED ELECTRONIC NICOTINE DELIVERY
 12 SYSTEMS.—

13 “(1) RESTRICTION.—Beginning on the date that
 14 is 30 days after the date of enactment of the Revers-
 15 ing the Youth Tobacco Epidemic Act of 2019, any fla-
 16 vored electronic nicotine delivery system that is a new
 17 tobacco product, including any liquid, solution, or
 18 other component or part or its aerosol, shall not con-
 19 tain an artificial or natural flavor (other than to-
 20 bacco) that is a characterizing flavor, including men-
 21 thol, mint, strawberry, grape, orange, clove, cin-
 22 namon, pineapple, vanilla, coconut, licorice, cocoa,
 23 chocolate, cherry, or coffee, unless the Secretary has
 24 issued a marketing order as described in paragraph
 25 (2). Nothing in this paragraph shall be construed to

1 *limit the Secretary’s authority to take action under*
2 *this section or other sections of this Act applicable to*
3 *any artificial or natural flavor, herb, or spice.*

4 “(2) *REVIEW.*—*The Secretary shall not issue a*
5 *marketing order under subsection (c)(1)(A)(i) or a*
6 *substantial equivalence order under subsection*
7 *(a)(2)(A)(i) for any electronic nicotine delivery sys-*
8 *tem, including any liquid, solution, or other compo-*
9 *nent or part or its aerosol, that contains an artificial*
10 *or natural flavor (other than tobacco) that is a char-*
11 *acterizing flavor, unless the Secretary issues an order*
12 *finding that the manufacturer has demonstrated*
13 *that—*

14 “(A) *use of the characterizing flavor—*

15 “(i) *will significantly increase the like-*
16 *lihood of smoking cessation among current*
17 *users of tobacco products; and*

18 “(ii) *will not increase the likelihood*
19 *that individuals who do not use tobacco*
20 *products, including youth, will start using*
21 *any tobacco product, including an electronic*
22 *nicotine delivery system; and*

23 “(B) *such electronic nicotine delivery sys-*
24 *tem is not more harmful to users than an elec-*

1 *tronic nicotine delivery system that does not con-*
 2 *tain any characterizing flavors.”.*

3 (3) *DEFINITION OF ELECTRONIC NICOTINE DE-*
 4 *LIVERY SYSTEM.*—Section 900 of the Federal Food,
 5 *Drug, and Cosmetic Act (21 U.S.C. 387) is amend-*
 6 *ed—*

7 (A) *by redesignating paragraphs (8)*
 8 *through (22) as paragraphs (9) through (23), re-*
 9 *spectively; and*

10 (B) *by inserting after paragraph (7) the fol-*
 11 *lowing new paragraph:*

12 “(8) *ELECTRONIC NICOTINE DELIVERY SYS-*
 13 *TEM.*—The term ‘*electronic nicotine delivery sys-*
 14 *tem*’—

15 “(A) *means any electronic device that deliv-*
 16 *ers nicotine, flavor, or another substance via an*
 17 *aerosolized solution to the user inhaling from the*
 18 *device (including e-cigarettes, e-hookah, e-cigars,*
 19 *vape pens, advanced refillable personal vapor-*
 20 *izers, and electronic pipes) and any component,*
 21 *liquid, part, or accessory of such a device, wheth-*
 22 *er or not sold separately; and*

23 “(B) *does not include a product that—*

24 “(i) *is approved by the Food and Drug*
 25 *Administration for sale as a tobacco ces-*

1 sation product or for another therapeutic
2 purpose; and

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

5 **SEC. 104. PROHIBITION AGAINST REMOTE RETAIL SALES.**

6 (a) *IN GENERAL.*—Paragraph (4) of section 906(d) of
7 *the Federal Food, Drug, and Cosmetic Act* (21 U.S.C.
8 387f(d)) is amended to read as follows:

9 “(4) *PROHIBITION AGAINST REMOTE RETAIL*
10 *SALES.*—

11 “(A) *PROHIBITION.*—Not later than 18
12 months after the date of enactment of the the Re-
13 versing the Youth Tobacco Epidemic Act of 2019,
14 the Secretary shall promulgate a final regulation
15 prohibiting the retail sale of all tobacco products
16 other than retail sales through a direct, face-to-
17 face exchange between a retailer and a consumer.

18 “(B) *EXCEPTION FOR CERTAIN CIGAR TO-*
19 *BACCO PRODUCTS.*—

20 “(i) *EXCEPTION.*—The regulation re-
21 quired by subparagraph (A) shall not apply
22 to tobacco products described in section
23 910(a)(2)(A)(iii).

24 “(ii) *APPLICABLE REQUIREMENTS.*—
25 Not later than 18 months after the date of

1 enactment of the the Reversing the Youth
2 Tobacco Epidemic Act of 2019, the Sec-
3 retary shall promulgate regulations regard-
4 ing the sale and distribution of tobacco
5 products described in section
6 910(a)(2)(A)(iii) that occur through means
7 other than a direct, face-to-face exchange be-
8 tween a retailer and a consumer in order to
9 prevent the sale and distribution of tobacco
10 products described in section
11 910(a)(2)(A)(iii) to individuals who have
12 not attained the minimum age established
13 by applicable law for the purchase of such
14 products, including requirements for age
15 verification.

16 “(C) *RELATION TO OTHER AUTHORITY.*—

17 *Nothing in this paragraph—*

18 “(i) *limits the authority of the Sec-*
19 *retary to take additional actions under the*
20 *other paragraphs of this subsection; or*

21 “(ii) *preempts the authority of a State*
22 *or local government to establish restrictions*
23 *on the retail sale of tobacco products that*
24 *are at least as restrictive as the prohibition*
25 *under subparagraph (A).”.*

1 (b) *APPLICABILITY.*—Section 906(d)(4) of the Federal
 2 *Food, Drug, and Cosmetic Act*, as in effect on the day before
 3 the date of enactment of this Act, shall continue to apply
 4 until the effective date of the regulations required by section
 5 906(d)(4) of such Act, as amended by subsection (a).

6 **SEC. 105. FEES APPLICABLE TO ALL TOBACCO PRODUCTS.**

7 (a) *INCREASE IN TOTAL AMOUNT.*—Section 919(b)(1)
 8 of the *Federal Food, Drug, and Cosmetic Act* (21 U.S.C.
 9 387s(b)(1)) is amended by striking subparagraph (K) and
 10 inserting the following subparagraphs:

11 “(K) For fiscal year 2019, \$712,000,000.

12 “(L) For fiscal year 2020, \$812,000,000.

13 “(M) For each subsequent fiscal year, the
 14 amount that was applicable for the previous fis-
 15 cal year, increased by the total percentage
 16 change that occurred in the Consumer Price
 17 Index for all urban consumers (all items; United
 18 States city average) for the 12-month period end-
 19 ing June 30 preceding the fiscal year.”.

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

22 (1) *IN GENERAL.*—Subparagraph (A) of section
 23 919(b)(2) of the *Federal Food, Drug, and Cosmetic*
 24 *Act* (21 U.S.C. 387s(b)(2)) is amended to read as fol-
 25 lows:

1 “(A) *IN GENERAL.*—

2 “(i) *FISCAL YEARS 2020 AND 2021.*—*For*
3 *fiscal years 2020 and 2021, user fees shall*
4 *be assessed and collected under subsection*
5 *(a) only with respect to the classes of to-*
6 *bacco products listed in subparagraph*
7 *(B)(i), and the total such user fees with re-*
8 *spect to each such class shall be an amount*
9 *that is equal to the applicable percentage of*
10 *each such class for the fiscal year multiplied*
11 *by the amount specified in paragraph (1)*
12 *for the fiscal year.*

13 “(ii) *SUBSEQUENT FISCAL YEARS.*—
14 *For fiscal year 2022 and each subsequent*
15 *fiscal year, user fees shall be assessed and*
16 *collected under subsection (a) with respect*
17 *to each class of tobacco products to which*
18 *this chapter applies (including tobacco*
19 *products that the Secretary by regulation*
20 *deems to be subject to this chapter), and the*
21 *total user fees with respect to each such*
22 *class shall be—*

23 “(I) *with respect to each class of*
24 *tobacco products listed in subpara-*
25 *graph (B)(i), an amount that is cal-*

1 *culated in the same way as the*
 2 *amounts calculated for fiscal years*
 3 *2020 and 2021 under clause (i), except*
 4 *that for purposes of fiscal years 2022*
 5 *and subsequent fiscal years, instead of*
 6 *multiplying the applicable percentage*
 7 *of each such class by ‘the amount speci-*
 8 *fied in paragraph (1) for the fiscal*
 9 *year’, the applicable percentage shall*
 10 *be multiplied by—*

11 *“(aa) the amount specified in*
 12 *paragraph (1) for the fiscal year,*
 13 *reduced by*

14 *“(bb) the total user fees as-*
 15 *essed and collected pursuant to*
 16 *subclause (II) for the fiscal year;*
 17 *and*

18 *“(II) with respect to each class of*
 19 *tobacco products to which this chapter*
 20 *applies but which is not listed in sub-*
 21 *paragraph (B)(i), an amount deter-*
 22 *mined pursuant to a formula under*
 23 *subparagraph (C).”.*

24 (2) *OTHER TOBACCO PRODUCTS.—Section*
 25 *919(b)(2) of the Federal Food, Drug, and Cosmetic*

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

4 “(C) *ALLOCATION FOR OTHER TOBACCO*
5 *PRODUCTS.—*

6 “(i) *IN GENERAL.—Beginning with fis-*
7 *cal year 2022, the total user fees assessed*
8 *and collected under subsection (a) each fis-*
9 *cal year with respect to each class of tobacco*
10 *products not listed in subparagraph (B)(i)*
11 *shall be an amount that is determined pur-*
12 *suant to a formula developed by the Sec-*
13 *retary by regulation using information re-*
14 *quired to be submitted under subparagraph*
15 *(D).*

16 “(ii) *ALLOCATION FOR OTHER TO-*
17 *BACCO PRODUCTS.—For each class of to-*
18 *bacco products not listed in subparagraph*
19 *(B)(i), the percentage of fees under the for-*
20 *mula under clause (i) for the respective fis-*
21 *cal year shall be equal to the percentage of*
22 *the gross domestic sales in the previous cal-*
23 *endar year that is attributable to such class*
24 *of tobacco products in such calendar year,*
25 *as determined by the Secretary.*

1 “(iii) *ALLOCATION OF ASSESSMENT*
 2 *WITHIN EACH CLASS OF OTHER TOBACCO*
 3 *PRODUCTS.—The percentage of the total*
 4 *user fee to be paid by each manufacturer or*
 5 *importer of tobacco products in a class not*
 6 *listed in subparagraph (B)(i) shall be deter-*
 7 *mined by the Secretary, based on the per-*
 8 *centage of the gross domestics sales of all*
 9 *such classes of tobacco products by all man-*
 10 *ufacturers and importers in the previous*
 11 *calendar year that is attributable to such*
 12 *manufacturer or importer.*

13 “(iv) *EFFECT OF FAILURE TO FINAL-*
 14 *IZE FORMULA ON TIME.—If the Secretary*
 15 *for any reason fails to finalize by fiscal*
 16 *year 2022 the formula required by this sub-*
 17 *paragraph for the assessment and collection*
 18 *of user fees for classes of tobacco products*
 19 *not listed in subparagraph (B)(i)—*

20 *“(I) the Secretary shall continue*
 21 *to assess and collect fees under sub-*
 22 *section (a) with respect to each class of*
 23 *tobacco products listed in subpara-*
 24 *graph (B)(i); and*

1 “(II) until the first fiscal year
2 commencing after the finalization of
3 such formula, the exception described
4 in subparagraph (A)(ii)(I) shall not
5 apply.

6 “(v) REVISIONS BY REGULATION.—Any
7 revisions to the formula promulgated pursu-
8 ant to this subparagraph shall be by regula-
9 tion.

10 “(vi) DEFINITION.—In this subpara-
11 graph, the term ‘gross domestic sales’ means
12 the total value in dollars of the sale or dis-
13 tribution by manufacturers and importers
14 of tobacco products in the United States in
15 classes not listed in subparagraph (B)(i), as
16 determined based on the aggregation of sales
17 data from every manufacturer and importer
18 of tobacco products that submits sales data
19 to the Secretary.

20 “(D) INFORMATION REQUIRED TO BE SUB-
21 MITTED.—Each manufacturer or importer of
22 any tobacco product shall submit to the Sec-
23 retary the information required under this sub-
24 paragraph by March 1, 2021, for calendar year
25 2020, by April 1, 2021, for the period of Janu-

ary 1, 2021, through March 30, 2021, and
monthly thereafter. Such information shall in-
clude—

“(i) the identification of the manufac-
turer or importer;

“(ii) the class or classes of tobacco
products sold by the manufacturer or im-
porter;

“(iii) the full listing of the finished to-
bacco products in a class not listed in sub-
paragraph (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 im-
porter 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

1 *determined for purposes of allocations under subsections (e)*
 2 *through (h) of section 625 of Public Law 108–357” and in-*
 3 *serting “shall be the percentage determined by the Sec-*
 4 *retary”.*

5 *(d) CONFORMING AMENDMENTS.—Section 919(b) of*
 6 *the Federal Food, Drug, and Cosmetic Act (21 U.S.C.*
 7 *387s(b)) is amended—*

8 *(1) by striking paragraph (5);*

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

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

13 *“(6) MEMORANDUM OF UNDERSTANDING.—The*
 14 *Secretary shall request the appropriate Federal agen-*
 15 *cy to enter into a memorandum of understanding*
 16 *that provides for the regular and timely transfer from*
 17 *the head of such agency to the Secretary of all nec-*
 18 *essary information regarding all tobacco product*
 19 *manufacturers and importers required to pay user*
 20 *fees. The Secretary shall maintain all disclosure re-*
 21 *strictions established by the head of such agency re-*
 22 *garding the information provided under the memo-*
 23 *randum of understanding.”.*

24 *(e) APPLICABILITY.—The amendments made by sub-*
 25 *sections (b), (c), and (d) apply beginning with fiscal year*

1 2022. Subject to the amendment made by subsection (a),
 2 section 919 of the Federal Food, Drug, and Cosmetic Act
 3 (21 U.S.C. 387s), as in effect on the day before the date
 4 of enactment of this Act, shall apply with respect to fiscal
 5 years preceding fiscal year 2022.

6 (f) *REPORT.*—For fiscal year 2020 and each subse-
 7 quent fiscal year for which fees are collected under section
 8 919 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
 9 387s), the Secretary of Health and Human Services, acting
 10 through the Commissioner of Food and Drugs, shall, by the
 11 end of the respective fiscal year, submit to the Congress fi-
 12 nancial and performance reports with respect to such fees.

13 **SEC. 106. REGULATION OF PRODUCTS CONTAINING SYN-**
 14 **THETIC NICOTINE.**

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

18 (1) not later than 1 year after the date of enact-
 19 ment of this Act, issue an interim final rule pro-
 20 viding for the regulation of products containing syn-
 21 thetic nicotine under the Federal Food, Drug, and
 22 Cosmetic Act (21 U.S.C. 301 et seq.); and

23 (2) not later than 2 years after such date of en-
 24 actment, issue a final rule providing for such regula-
 25 tion.

1 (b) *SYNTHETIC NICOTINE DEFINED.*—*In this section,*
 2 *the term “synthetic nicotine” means nicotine that is not*
 3 *made or derived from tobacco.*

4 **SEC. 107. UPDATE TO YOUTH TOBACCO PREVENTION PUB-**
 5 **LIC AWARENESS CAMPAIGNS.**

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

9 (1) *review all public health awareness campaigns*
 10 *of the Department of Health and Human Services de-*
 11 *signed to educate at-risk individuals about the harm-*
 12 *ful effects of tobacco use, including the use of e-ciga-*
 13 *rettes and other electronic nicotine delivery systems;*
 14 *and*

15 (2) *as applicable, modify such campaigns to in-*
 16 *clude awareness and education materials designated*
 17 *for individuals who are 18 to 21 years of age.*

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

1 **SEC. 108. EXEMPTION FROM PREMARKET APPROVAL OF**
 2 **CERTAIN TOBACCO PRODUCTS.**

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

6 (1) in subparagraph (A)—

7 (A) in clause (i)(II), by striking “or”;

8 (B) in clause (ii), by striking the period at
 9 the end and inserting “; or”; and

10 (C) by adding at the end the following:

11 “(iii) subject to subparagraph (C), for
 12 the period beginning on the date of the en-
 13 actment of the Reversing the Youth Tobacco
 14 Epidemic Act of 2019 and ending on Sep-
 15 tember 30, 2028, the tobacco product is a
 16 cigar and—

17 “(I) is wrapped in whole tobacco
 18 leaf;

19 “(II) contains a 100-percent leaf
 20 tobacco binder;

21 “(III) contains primarily long
 22 filler tobacco;

23 “(IV) does not have a character-
 24 izing flavor other than tobacco;

25 “(V) weighs more than 6 pounds
 26 per 1000 units;

1 “(VI) has no filter, tip, or non-to-
2 bacco mouthpiece;

3 “(VII)(aa) is made by combining
4 manually the wrapper, filler, and
5 binder and is capped by hand; or

6 “(bb) has a homogenized tobacco
7 leaf binder and is made in the United
8 States using human hands to lay the
9 100-percent leaf tobacco binder onto
10 only one machine that bunches, wraps,
11 and caps each individual cigar; and

12 “(VIII) has a retail price (after
13 discounts or coupons) per cigar of no
14 less than—

15 “(aa) for calendar years
16 2019 and 2020, \$12; and

17 “(bb) for each subsequent cal-
18 endar year, \$12 multiplied by
19 any percent increase in the Con-
20 sumer Price Index for all urban
21 consumers (all items; U.S. city
22 average) since calendar year
23 2020.”; and

24 (2) by adding at the end the following:

25 “(C) DETERMINATION OF APPLICABILITY.—

1 “(i) *IN GENERAL.*—*The Secretary*
2 *shall, notwithstanding subparagraph*
3 *(A)(iii) or any determination of substantial*
4 *equivalence, if any of the conditions speci-*
5 *fied in clause (ii) are met—*

6 “(I) *withdraw any exemption ap-*
7 *plicable to a tobacco product or prod-*
8 *ucts described in such subparagraph;*

9 “(II) *require that applications for*
10 *review under this section be submitted*
11 *with respect to such product or prod-*
12 *ucts; and*

13 “(III) *require that manufacturers*
14 *may only market such tobacco product*
15 *after the issuance of an order under*
16 *subsection (c)(1)(A)(i) with respect to*
17 *such product or products.*

18 “(ii) *CONDITIONS.*—*The conditions*
19 *specified in this clause are that—*

20 “(I) *the Secretary determines that*
21 *the use of a tobacco product or prod-*
22 *ucts described in subparagraph (A)(iii)*
23 *has resulted in an emerging public*
24 *health threat;*

1 “(II) data from a National Youth
 2 Tobacco Survey (or successor survey)
 3 conducted after the date of the enact-
 4 ment of the Reversing the Youth To-
 5 bacco Epidemic Act of 2019 identifies
 6 a rise in youth usage of tobacco prod-
 7 ucts described in section
 8 910(a)(2)(A)(iii); or

9 “(III) the Secretary determines
 10 that a tobacco product or products no
 11 longer meets the criteria specified in
 12 such subparagraph.”.

13 (b) NATIONAL ACADEMIES STUDY AND REPORT.—

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

20 (A) the public health impact of having to-
 21 bacco products described in subsection
 22 (a)(2)(A)(iii) of section 910 of the Federal Food,
 23 Drug, and Cosmetic Act (21 U.S.C. 387j(a)(2)),
 24 as amended by subsection (a), exempt from pre-
 25 market review under such section;

1 (B) the youth usage of such tobacco prod-
2 ucts; and

3 (C) the market share of such products.

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

10 **SEC. 109. PUBLIC EDUCATION.**

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

14 “(g) *EDUCATION ON TOBACCO PRODUCTS.*—

15 “(1) *IN GENERAL.*—Not later than 6 months
16 after the date of the enactment of the Reversing the
17 Youth Tobacco Epidemic Act of 2019, the Secretary of
18 Health and Human Services, acting through the Com-
19 missioner of Food and Drugs, shall provide edu-
20 cational materials for health care providers, members
21 of the public, and law enforcement officials, regard-
22 ing—

23 “(A) the authority of the Food and Drug
24 Administration with respect to the regulation of

1 tobacco products (including enforcement of such
2 regulation);

3 “(B) the processes of the Food and Drug
4 Administration for enforcing restrictions on the
5 manufacture and sale of tobacco products;

6 “(C) the prohibition on characterizing fla-
7 vors in tobacco products and the under section
8 907(a)(1) and the exception from such prohibi-
9 tion under subparagraph (C) of such section;

10 “(D) the public health impact of tobacco
11 products with characterizing flavors; and

12 “(E) other information as the Secretary de-
13 termines appropriate.

14 “(2) CONTENT.—Educational materials provided
15 under paragraph (1) may include—

16 “(A) explanations of key statutory and reg-
17 ulatory terms, including the terms ‘tobacco prod-
18 uct,’ ‘component parts,’ ‘accessories,’ ‘con-
19 stituent,’ ‘additive,’ ‘tobacco product manufac-
20 turer,’ and ‘characterizing flavor’;

21 “(B) an explanation of the Food and Drug
22 Administration’s jurisdiction to regulate tobacco
23 products, including tobacco products with char-
24 acterizing flavors under section 907(a)(1);

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

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

8 “(E) information on resources available re-
 9 lated to smoking cessation.

10 “(3) *FORMAT*.—Educational materials provided
 11 under paragraph (1) may be—

12 “(A) published in any format, including an
 13 Internet website, video, fact sheet, infographic,
 14 webinar, or other format, as the Secretary deter-
 15 mines is appropriate and applicable; and

16 “(B) tailored for the unique needs of health
 17 care providers, members of the public, law en-
 18 forcement officers, and other audiences, as the
 19 Secretary determines appropriate.”.

20 **SEC. 110. REGULATIONS FOR RECORDKEEPING CON-**
 21 **CERNING TRACKING AND TRACING.**

22 *The Secretary of Health and Human Services, acting*
 23 *through the Commissioner of Food and Drugs, shall pro-*
 24 *mulgate the regulations required by section 920(b) of the*

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

3 *(1) Not later than 1 year after the date of enact-*
 4 *ment of this Act, the Secretary shall issue proposed*
 5 *regulations.*

6 *(2) Not later than 2 years after the date of enact-*
 7 *ment of this Act, the Secretary shall promulgate final*
 8 *regulations.*

9 ***TITLE II—FEDERAL TRADE*** 10 ***COMMISSION***

11 ***SEC. 201. ADVERTISING OF TOBACCO PRODUCTS.***

12 *(a) ADVERTISING OF ELECTRONIC NICOTINE DELIV-*
 13 *ERY SYSTEMS.—*

14 *(1) IN GENERAL.—It shall be unlawful—*

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

19 *(B) to market, advertise, promote, or en-*
 20 *dorse, or to compensate any person for the mar-*
 21 *keting, advertising, promotion, or endorsement*
 22 *of, any electronic nicotine delivery system with-*
 23 *out clearly disclosing that the communication is*
 24 *an advertisement, unless the communication is*
 25 *unambiguously identifiable as an advertisement.*

1 (2) *ENFORCEMENT BY COMMISSION.*—

2 (A) *UNFAIR OR DECEPTIVE ACTS OR PRAC-*
 3 *TICES.*—*A violation of paragraph (1) shall be*
 4 *treated as a violation of a regulation under sec-*
 5 *tion 18(a)(1)(B) of the Federal Trade Commis-*
 6 *sion Act (15 U.S.C. 57a(a)(1)(B)) regarding un-*
 7 *fair or deceptive acts or practices.*

8 (B) *POWERS OF COMMISSION.*—*The Com-*
 9 *mission shall enforce paragraph (1) in the same*
 10 *manner, by the same means, and with the same*
 11 *jurisdiction, powers, and duties as though all ap-*
 12 *plicable terms and provisions of the Federal*
 13 *Trade Commission Act (15 U.S.C. 41 et seq.)*
 14 *were incorporated into and made a part of this*
 15 *Act. Any person who violates such paragraph*
 16 *shall be subject to the penalties and entitled to*
 17 *the privileges and immunities provided in the*
 18 *Federal Trade Commission Act.*

19 (3) *ENFORCEMENT BY STATE ATTORNEYS GEN-*
 20 *ERAL.*—

21 (A) *IN GENERAL.*—*If the attorney general of*
 22 *a State has reason to believe a violation of para-*
 23 *graph (1) has occurred or is occurring, the attor-*
 24 *ney general, in addition to any authority the at-*
 25 *torney general may have to bring an action in*

1 *State court under the law of the State, may*
2 *bring a civil action in any court of competent*
3 *jurisdiction to—*

4 *(i) enjoin further such violation by the*
5 *defendant;*

6 *(ii) enforce compliance with such para-*
7 *graph;*

8 *(iii) obtain civil penalties in the same*
9 *amount as may be obtained by the Commis-*
10 *sion in a civil action under section 5(m) of*
11 *the Federal Trade Commission Act (15*
12 *U.S.C. 45(m)); or*

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

16 *(B) NOTICE.—Before filing an action under*
17 *subparagraph (A), the attorney general of a*
18 *State shall provide to the Commission a written*
19 *notice of such action and a copy of the complaint*
20 *for such action. If the attorney general deter-*
21 *mines that it is not feasible to provide the notice*
22 *described in this subparagraph before the filing*
23 *of the action, the attorney general shall provide*
24 *written notice of the action and a copy of the*

1 *complaint to the Commission immediately upon*
2 *the filing of the action.*

3 (C) *AUTHORITY OF FEDERAL TRADE COM-*
4 *MISSION.—*

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

9 *(I) to intervene in the action;*

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

13 *(III) to file petitions for appeal.*

14 (ii) *LIMITATION ON STATE ACTION*
15 *WHILE FEDERAL ACTION IS PENDING.—If*
16 *the Commission has instituted a civil action*
17 *for violation of paragraph (1) (referred to*
18 *in this clause as the “Federal action”), no*
19 *attorney general of a State may bring an*
20 *action under subparagraph (A) during the*
21 *pendency of the Federal action against any*
22 *defendant named in the complaint in the*
23 *Federal action for any violation of such*
24 *paragraph alleged in such complaint.*

1 (D) RELATIONSHIP WITH STATE-LAW
2 CLAIMS.—

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

8 (ii) ASSERTION IN SAME CIVIL AC-
9 TION.—*If the attorney general of a State*
10 *has authority to bring an action under*
11 *State law for acts or practices that also vio-*
12 *late paragraph (1), the attorney general*
13 *may assert the State-law claim and the*
14 *claim for violation of such paragraph in the*
15 *same civil action.*

16 (E) ACTIONS BY OTHER STATE OFFI-
17 CIALS.—*In addition to civil actions brought by*
18 *attorneys general under subparagraph (A), any*
19 *other consumer protection officer of a State who*
20 *is authorized by the State to do so may bring a*
21 *civil action under such subparagraph, subject to*
22 *the same requirements and limitations that*
23 *apply under this paragraph to civil actions*
24 *brought by attorneys general.*

1 (4) *RULEMAKING AUTHORITY.*—*The Commission*
2 *may promulgate regulations under section 553 of title*
3 *5, United States Code, to implement paragraph (1).*

4 (b) *REPORT TO CONGRESS ON TOBACCO PRODUCT AD-*
5 *VERTISING.*—

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

13 (A) *Information on domestic sales and ad-*
14 *vertising and promotional activity by the manu-*
15 *facturers that have the largest market shares of*
16 *the product category.*

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

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

22 (A) *Cigarettes.*

23 (B) *Cigars.*

24 (C) *Smokeless tobacco.*

25 (D) *Electronic nicotine delivery systems.*

1 (c) *PRESERVATION OF AUTHORITY.*—*Nothing in this*
 2 *section may be construed in any way to limit the Commis-*
 3 *sion’s authority under any other provision of law.*

4 (d) *DEFINITIONS.*—*In this section:*

5 (1) *CIGAR.*—*The term “cigar” means a tobacco*
 6 *product that—*

7 (A) *is not a cigarette; and*

8 (B) *is a roll of tobacco wrapped in leaf to-*
 9 *bacco or any substance containing tobacco.*

10 (2) *CIGARETTE.*—*The term “cigarette” has the*
 11 *meaning given such term in section 900 of the Fed-*
 12 *eral Food, Drug, and Cosmetic Act (21 U.S.C. 387).*

13 (3) *COMMISSION.*—*The term “Commission”*
 14 *means the Federal Trade Commission.*

15 (4) *ELECTRONIC NICOTINE DELIVERY SYSTEM.*—
 16 *The term “electronic nicotine delivery system”—*

17 (A) *means any electronic device that deliv-*
 18 *ers nicotine, flavor, or another substance via an*
 19 *aerosolized solution to the user inhaling from the*
 20 *device (including e-cigarettes, e-hookah, e-cigars,*
 21 *vape pens, advanced refillable personal vapor-*
 22 *izers, and electronic pipes) and any component,*
 23 *liquid, part, or accessory of such a device, wheth-*
 24 *er or not sold separately; and*

25 (B) *does not include a product that—*

1 (i) is approved by the Food and Drug
2 Administration for sale as a tobacco ces-
3 sation product or for another therapeutic
4 purpose; and

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

7 (5) *ENDORSE*.—The term “endorse” means to
8 communicate an advertising message (including a
9 verbal statement, demonstration, or depiction of the
10 name, signature, likeness, or other identifying per-
11 sonal characteristics of an individual or the name or
12 seal of an organization) that consumers are likely to
13 believe reflects the opinions, beliefs, findings, or expe-
14 riences of a party other than the sponsoring adver-
15 tiser, even if the views expressed by such party are
16 identical to those of the sponsoring advertiser.

17 (6) *NICOTINE*.—The term “nicotine” has the
18 meaning given such term in section 900 of the Fed-
19 eral Food, Drug, and Cosmetic Act (21 U.S.C. 387).

20 (7) *SMOKELESS TOBACCO*.—The term “smokeless
21 tobacco” has the meaning given such term in section
22 900 of the Federal Food, Drug, and Cosmetic Act (21
23 U.S.C. 387).

24 (8) *TOBACCO PRODUCT*.—The term “tobacco
25 product” has the meaning given such term in section

1 201 of the Federal Food, Drug, and Cosmetic Act (21
2 U.S.C. 321).

3 ***TITLE III—PUBLIC HEALTH***
4 ***PROGRAMS***

5 ***SEC. 301. OUTREACH TO MEDICALLY UNDERSERVED COM-***
6 ***MUNITIES.***

7 *The Secretary shall ensure that programs at the Cen-*
8 *ters for Disease Control and Prevention related to outreach*
9 *to medically underserved communities, including racial*
10 *and ethnic minority populations, include efforts to educate*
11 *and provide guidance regarding effective evidence-based*
12 *strategies—*

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

15 *(2) for smoking cessation and the cessation of the*
16 *use of e-cigarettes and electronic nicotine delivery sys-*
17 *tems.*

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

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

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

7 (2) *the development of improved communication*
8 *and outreach tools to reach populations in medically*
9 *underserved communities, particularly racial and eth-*
10 *nic minority populations, addicted to tobacco and e-*
11 *cigarette products; and*

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

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

22 (c) *AUTHORIZATION OF APPROPRIATIONS.—There are*
23 *authorized to be appropriated to carry out this section,*
24 *\$3,000,000 for each of fiscal years 2020 through 2024.*

1 **TITLE IV—NICOTINE OR VAPING**
 2 **ACCESS PROTECTION AND**
 3 **ENFORCEMENT**

4 **SECTION 401. SHORT TITLE.**

5 *This title may be cited as the “Nicotine or Vaping Ac-*
 6 *cess Protection and Enforcement Act of 2019” or the “NO*
 7 *VAPE Act of 2019”.*

8 **SEC. 402. INCREASING CIVIL PENALTIES APPLICABLE TO**
 9 **CERTAIN VIOLATIONS OF RESTRICTIONS ON**
 10 **SALE AND DISTRIBUTION OF TOBACCO PROD-**
 11 **UCTS.**

12 *(a) PENALTIES.—Subparagraph (A) of section*
 13 *103(q)(2) of the Family Smoking Prevention and Tobacco*
 14 *Control Act (21 U.S.C. 333 note) is amended to read as*
 15 *follows:*

16 *“(A) IN GENERAL.—The amount of the civil*
 17 *penalty to be applied for violations of restric-*
 18 *tions promulgated under section 906(d), as de-*
 19 *scribed in paragraph (1), shall be as follows:*

20 *“(i) With respect to a retailer with an*
 21 *approved training program, the amount of*
 22 *the civil penalty shall not exceed—*

23 *“(I) in the case of the first viola-*
 24 *tion, \$0, together with the issuance of*
 25 *a warning letter to the retailer;*

1 “(II) in the case of a second viola-
2 tion within a 12-month period, \$500;

3 “(III) in the case of a third viola-
4 tion within a 24-month period, \$1,000;

5 “(IV) in the case of a fourth viola-
6 tion within a 24-month period, \$4,000;

7 “(V) in the case of a fifth viola-
8 tion within a 36-month period,
9 \$10,000; and

10 “(VI) in the case of a sixth or sub-
11 sequent violation within a 48-month
12 period, \$20,000 as determined by the
13 Secretary on a case-by-case basis.

14 “(ii) With respect to a retailer that
15 does not have an approved training pro-
16 gram, the amount of the civil penalty shall
17 not exceed—

18 “(I) in the case of the first viola-
19 tion, \$500;

20 “(II) in the case of a second viola-
21 tion within a 12-month period, \$1,000;

22 “(III) in the case of a third viola-
23 tion within a 24-month period, \$2,000;

24 “(IV) in the case of a fourth viola-
25 tion within a 24-month period, \$4,000;

1 “(V) in the case of a fifth viola-
 2 tion within a 36-month period,
 3 \$10,000; and

4 “(VI) in the case of a sixth or sub-
 5 sequent violation within a 48-month
 6 period, \$20,000 as determined by the
 7 Secretary on a case-by-case basis.”.

8 (b) *APPLICABILITY.*—The amendment made by sub-
 9 section (a) applies with respect to a violation of a restric-
 10 tion promulgated under section 906(d)(1) of the Federal
 11 Food, Drug, and Cosmetic Act (21 U.S.C. 387f(d)(1)), as
 12 described in section 103(q)(1) of the Family Smoking Pre-
 13 vention and Tobacco Control Act (21 U.S.C. 333 note), oc-
 14 curring on or after the date that is 6 months after the enact-
 15 ment of this Act. The penalties specified in such section
 16 103(q)(1), as in effect on the day before such date, shall
 17 continue to apply to violations occurring before such date.

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

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

22 (1) complete a study on—

23 (A) the relationship of e-cigarettes to to-
 24 bacco cessation;

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

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

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

Union Calendar No. 324

116TH CONGRESS
2D Session

H. R. 2339

[Report No. 116-402]

A BILL

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

FEBRUARY 21, 2020

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