

116TH CONGRESS
2^D SESSION

H. R. 2339

AN ACT

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

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

1 **SECTION 1. SHORT TITLE.**

2 This Act may be cited as the “Protecting American
3 Lungs and Reversing the Youth Tobacco Epidemic Act of
4 2020”.

5 **SEC. 2. TABLE OF CONTENTS.**

6 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 alternative nicotine.
- Sec. 107. Update to youth tobacco prevention public awareness campaigns.
- Sec. 108. Exemption from premarket review 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.
- Sec. 303. Public awareness, education, and prevention campaign.
- Sec. 304. Tobacco cessation treatment grants to health centers.
- Sec. 305. Grants for research.

TITLE IV—NICOTINE OR VAPING ACCESS PROTECTION AND ENFORCEMENT

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

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

- Sec. 501. Imposition of tax on nicotine for use in vaping, etc.

TITLE VI—FURTHER HEALTH INVESTMENTS

- Sec. 601. Waiving Medicare coinsurance for colorectal cancer screening tests.
- Sec. 602. Safe harbor for high deductible health plans without deductible for certain inhalers.

1 **TITLE I—FOOD AND DRUG**
2 **ADMINISTRATION**

3 **SEC. 101. CIGARETTE GRAPHIC HEALTH WARNINGS.**

4 (a) **ISSUANCE DEADLINES.**—Not later than March
5 15, 2020, the Secretary of Health and Human Services,
6 acting through the Commissioner of Food and Drugs,
7 shall publish a final rule pursuant to section 4(d) of the
8 Federal Cigarette Labeling and Advertising Act (15
9 U.S.C. 1333(d)). If the Secretary fails to promulgate such
10 final rule by March 15, 2020, then the proposed rule titled
11 “Tobacco Products; Required Warnings for Cigarette
12 Packages and Advertisements” published by the Food and
13 Drug Administration on August 16, 2019 (84 Fed. Reg.
14 42754) shall be treated as a final rule beginning on March
15 16, 2020.

16 (b) **CONFORMING CHANGE.**—The first section 4(d) of
17 the Federal Cigarette Labeling and Advertising Act (15
18 U.S.C. 1333(d)) (relating to graphic labeling statements)
19 is amended by striking “Not later than 24 months after
20 the date of enactment of the Family Smoking Prevention
21 and Tobacco Control Act, the Secretary” and inserting
22 “The Secretary”.

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

3 (a) IN GENERAL.—Not later than 1 year after the
4 date of enactment of this Act, the Secretary of Health and
5 Human Services, acting through the Commissioner of
6 Food and Drugs, shall promulgate a final rule amending
7 part 1140 of subchapter K of title 21, Code of Federal
8 Regulations, to apply the provisions of such part 1140 to
9 all tobacco products, as applicable, to which chapter IX
10 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
11 387a et seq.) applies pursuant to section 901(b) of such
12 Act (21 U.S.C. 387a(b)), as amended by section 103(a)
13 of this Act.

14 (b) EFFECTIVE DATE.—The final rule required by
15 subsection (a) shall take effect on the date that is 2 years
16 after the date of enactment of this Act.

17 **SEC. 103. REDUCING CHILD AND ADOLESCENT NICOTINE**
18 **ADDICTION.**

19 (a) APPLICABILITY TO ALL TOBACCO PRODUCTS.—

20 (1) IN GENERAL.—Subsection (b) of section
21 901 of the Federal Food, Drug, and Cosmetic Act
22 (21 U.S.C. 387a) is amended to read as follows:

23 “(b) APPLICABILITY.—This chapter shall apply to all
24 tobacco products.”.

25 (2) RULE OF CONSTRUCTION.—Paragraph (1)
26 and the amendment made thereby shall not be con-

1 strued to limit the applicability of chapter IX of the
2 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
3 387a et seq.) to—

4 (A) products that were listed in section
5 901(b) of such Act as in effect on the day be-
6 fore the date of enactment of this Act; and

7 (B) products that were deemed by regula-
8 tion to be subject to such chapter pursuant to
9 section 901(b) of such Act as in effect on the
10 day before the date of enactment of this Act.

11 (b) PROHIBITING FLAVORING OF TOBACCO PROD-
12 UCTS.—

13 (1) PROHIBITION.—

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

18 “(A) SPECIAL RULES.—

19 “(i) IN GENERAL.—Beginning on the
20 date that is 1 year after the date of enact-
21 ment of the Protecting American Lungs
22 and Reversing the Youth Tobacco Epi-
23 demic Act of 2020, a tobacco product (in-
24 cluding its components, parts, and acces-
25 sories, including the tobacco, filter, or

1 paper) that is not an electronic nicotine de-
2 livery system shall not contain, as a con-
3 stituent (including a smoke constituent) or
4 additive, an artificial or natural flavor
5 (other than tobacco) that is a character-
6 izing flavor of the tobacco product or to-
7 bacco smoke or an herb or spice, including
8 menthol, mint, mango, strawberry, grape,
9 orange, clove, cinnamon, pineapple, vanilla,
10 coconut, licorice, cocoa, chocolate, cherry,
11 or coffee.

12 “(ii) RULE OF CONSTRUCTION.—

13 Nothing in this subparagraph shall be con-
14 strued to limit the Secretary’s authority to
15 take action under this section or other sec-
16 tions of this Act applicable to any artificial
17 or natural flavor, herb, or spice.

18 “(iii) APPLICABILITY TO CERTAIN IN-

19 DIVIDUALS.—Notwithstanding any provi-
20 sion of this Act, no individual who pur-
21 chases for individual consumption, pos-
22 sesses for individual consumption, or con-
23 sumes, a tobacco product that is in viola-
24 tion of the prohibition under this subpara-
25 graph, including a tobacco product that

1 contains a characterizing flavor of menthol,
2 shall be subject to any criminal penalty
3 under this Act for such purchase, posses-
4 sion, or consumption, nor shall such pur-
5 chase, possession, or consumption be used
6 as a justification to stop, search, or con-
7 duct any other investigative measure
8 against any individual.”.

9 (B) SAVINGS PROVISION.—Section
10 907(a)(1) of the Federal Food, Drug, and Cos-
11 metic Act (21 U.S.C. 387g(a)(1)), as in effect
12 on the date of enactment of this Act, shall re-
13 main in effect until the amendment made to
14 such section 907(a)(1) by this paragraph takes
15 effect.

16 (2) FLAVORED ELECTRONIC NICOTINE DELIV-
17 ERY SYSTEM.—Section 910 of the Federal Food,
18 Drug, and Cosmetic Act (21 U.S.C. 387j) is amend-
19 ed by inserting at the end the following:

20 “(h) FLAVORED ELECTRONIC NICOTINE DELIVERY
21 SYSTEMS.—

22 “(1) RESTRICTION.—Beginning on the date
23 that is 30 days after the date of enactment of the
24 Protecting American Lungs and Reversing the
25 Youth Tobacco Epidemic Act of 2020, any flavored

1 electronic nicotine delivery system that is a new to-
2 bacco product, including any solution or other com-
3 ponent or part (such as a liquid or its aerosol) shall
4 not contain an artificial or natural flavor (other than
5 tobacco) that is a characterizing flavor, including
6 menthol, mint, mango, strawberry, grape, orange,
7 clove, cinnamon, pineapple, vanilla, coconut, licorice,
8 cocoa, chocolate, cherry, or coffee, unless the Sec-
9 retary has issued a marketing order as described in
10 paragraph (2). Nothing in this paragraph shall be
11 construed to limit the Secretary's authority to take
12 action under this section or other sections of this
13 Act applicable to any artificial or natural flavor,
14 herb, or spice.

15 “(2) REVIEW.—The Secretary shall not issue a
16 marketing order under subsection (c)(1)(A)(i) or a
17 substantial equivalence order under subsection
18 (a)(2)(A)(i) for any electronic nicotine delivery sys-
19 tem, including any liquid, solution, or other compo-
20 nent or part or its aerosol, that contains an artificial
21 or natural flavor (other than tobacco) that is a char-
22 acterizing flavor, unless the Secretary issues an
23 order finding that the manufacturer has dem-
24 onstrated that—

25 “(A) use of the characterizing flavor—

1 “(i) will significantly increase the like-
2 lihood of smoking cessation among current
3 users of tobacco products; and

4 “(ii) will not increase the likelihood
5 that individuals who do not use tobacco
6 products, including youth, will start using
7 any tobacco product, including an elec-
8 tronic nicotine delivery system; and

9 “(B) such electronic nicotine delivery sys-
10 tem is not more harmful to users than an elec-
11 tronic nicotine delivery system that does not
12 contain any characterizing flavors.”.

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

17 (A) by redesignating paragraphs (8)
18 through (22) as paragraphs (9) through (23),
19 respectively; and

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

22 “(8) ELECTRONIC NICOTINE DELIVERY SYS-
23 TEM.—The term ‘electronic nicotine delivery system’
24 means a tobacco product that is an electronic device
25 that delivers nicotine, flavor, or another substance

1 via an aerosolized solution to the user inhaling from
2 the device (including e-cigarettes, e-hookah, e-cigars,
3 vape pens, advanced refillable personal vaporizers,
4 and electronic pipes) and any component, liquid,
5 part, or accessory of such a device, whether or not
6 sold separately.”.

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

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

16 (a) IN GENERAL.—Paragraph (4) of section 906(d)
17 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
18 387f(d)) is amended to read as follows:

19 “(4) PROHIBITION AGAINST REMOTE RETAIL
20 SALES.—

21 “(A) PROHIBITION.—Not later than 18
22 months after the date of enactment of the Pro-
23 tecting American Lungs and Reversing the
24 Youth Tobacco Epidemic Act of 2020, the Sec-
25 retary shall promulgate a final regulation pro-

1 hibiting the retail sale of all tobacco products
2 other than retail sales through a direct, face-to-
3 face exchange between a retailer and a con-
4 sumer.

5 “(B) EXCEPTION FOR CERTAIN CIGAR TO-
6 BACCO PRODUCTS.—

7 “(i) EXCEPTION.—The regulation re-
8 quired by subparagraph (A) shall not apply
9 to tobacco products described in section
10 910(a)(2)(A)(iii).

11 “(ii) APPLICABLE REQUIREMENTS.—
12 Not later than 18 months after the date of
13 enactment of the Protecting American
14 Lungs and Reversing the Youth Tobacco
15 Epidemic Act of 2020, the Secretary shall
16 promulgate regulations regarding the sale
17 and distribution of tobacco products de-
18 scribed in section 910(a)(2)(A)(iii) that
19 occur through means other than a direct,
20 face-to-face exchange between a retailer
21 and a consumer in order to prevent the
22 sale and distribution of tobacco products
23 described in section 910(a)(2)(A)(iii) to in-
24 dividuals who have not attained the min-
25 imum age established by applicable law for

1 the purchase of such products, including
2 requirements for age verification.

3 “(C) RELATION TO OTHER AUTHORITY.—

4 Nothing in this paragraph—

5 “(i) limits the authority of the Sec-
6 retary to take additional actions under
7 other provisions of this Act; or

8 “(ii) preempts the authority of a State
9 or local government to establish restric-
10 tions on the retail sale of tobacco products
11 that are in addition to, or more stringent
12 than, the prohibition under subparagraph
13 (A).”.

14 (b) APPLICABILITY.—Section 906(d)(4) of the Fed-
15 eral Food, Drug, and Cosmetic Act, as in effect on the
16 day before the date of enactment of this Act, shall con-
17 tinue to apply until the effective date of the regulations
18 required by section 906(d)(4) of such Act, as amended by
19 subsection (a).

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

21 (a) INCREASE IN TOTAL AMOUNT.—Section
22 919(b)(1) of the Federal Food, Drug, and Cosmetic Act
23 (21 U.S.C. 387s(b)(1)) is amended by striking subpara-
24 graph (K) and inserting the following subparagraphs:

1 “(K) For fiscal years 2019 and 2020,
2 \$712,000,000.

3 “(L) For fiscal year 2021, \$812,000,000.

4 “(M) For each subsequent fiscal year, the
5 amount that was applicable for the previous fis-
6 cal year, increased by the total percentage
7 change that occurred in the Consumer Price
8 Index for all urban consumers (all items;
9 United States city average) for the 12-month
10 period ending June 30 preceding the fiscal
11 year.”.

12 (b) APPLICABILITY.—

13 (1) FISCAL YEARS 2020 AND 2021.—Except as
14 amended by subsection (a), for fiscal years 2020 and
15 2021, section 919 of the Federal Food, Drug, and
16 Cosmetic Act (21 U.S.C. 387s) shall apply as in ef-
17 fect on the day before the date of enactment of this
18 Act.

19 (2) SUBSEQUENT FISCAL YEARS.—The amend-
20 ments made by subsections (c) through (f) apply be-
21 ginning with fiscal year 2022.

22 (c) ALLOCATIONS OF ASSESSMENT BY CLASS OF TO-
23 BACCO PRODUCTS.—Paragraph (2) of section 919(b) of
24 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
25 387s(b)) is amended to read as follows:

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

3 “(A) IN GENERAL.—The total user fees as-
4 sessed and collected under subsection (a) each
5 fiscal year (beginning with fiscal year 2022)
6 with respect to each class of tobacco products
7 to which this chapter applies shall be an
8 amount that is equal to the applicable percent-
9 age of each class for the fiscal year multiplied
10 by the amount specified in paragraph (1) for
11 the fiscal year.

12 “(B) APPLICABLE PERCENTAGE.—

13 “(i) IN GENERAL.—For purposes of
14 subparagraph (A), the applicable percent-
15 age for a fiscal year for each class of to-
16 bacco product shall be the percentage de-
17 termined by dividing—

18 “(I) the product of the gross do-
19 mestic volume of the class multiplied
20 by the tax rate applicable to the class
21 under section 5701 of the Internal
22 Revenue Code of 1986; and

23 “(II) the sum of the products de-
24 termined under subelause (I) for all
25 classes of tobacco products.

1 “(ii) DEFINITION.—For purposes of
2 clause (i), the term ‘gross domestic volume’
3 means the volume of tobacco products—

4 “(I) removed (as defined by sec-
5 tion 5702 of the Internal Revenue
6 Code of 1986); and

7 “(II) not exempt from tax under
8 chapter 52 of the Internal Revenue
9 Code of 1986 at the time of their re-
10 removal under that chapter or the Har-
11 monized Tariff Schedule of the United
12 States (19 U.S.C. 1202).”.

13 (d) ALLOCATION OF ASSESSMENT WITHIN EACH
14 CLASS OF TOBACCO PRODUCT.—Section 919(b)(4) of the
15 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
16 387s(b)(4)) is amended by striking “shall be the percent-
17 age determined for purposes of allocations under sub-
18 sections (e) through (h) of section 625 of Public Law 108–
19 357” and inserting “shall be allocated on a pro rata basis
20 among the manufacturers and importers of each class of
21 tobacco products to which this chapter applies based on
22 the percentage share of each manufacturer’s or importer’s
23 share of gross domestic volume within such class on a
24 quarterly basis, based on data for the second preceding
25 quarter”.

1 (e) OTHER AMENDMENTS.—Section 919(b) of the
2 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
3 387s(b)) is amended—

4 (1) by striking paragraph (5);

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

7 (3) by amending paragraph (6), as redesi-
8 gated, to read as follows:

9 “(6) MEMORANDUM OF UNDERSTANDING; RE-
10 PORTING.—

11 “(A) TRANSFER OF INFORMATION.—The
12 Secretary shall request the appropriate Federal
13 agency to enter into a memorandum of under-
14 standing that provides for the regular and time-
15 ly transfer from the head of such agency to the
16 Secretary of all necessary information regarding
17 all tobacco product manufacturers and import-
18 ers required to pay user fees. The Secretary
19 shall maintain all disclosure restrictions estab-
20 lished by the head of such agency regarding the
21 information provided under the memorandum of
22 understanding.

23 “(B) REPORTING.—

24 “(i) MANUFACTURER REPORTING.—

25 The Secretary may require the manufac-

1 turers and importers of each class of to-
2 bacco products to which this chapter ap-
3 plies to submit such information, by such
4 time, and in such manner, as the Secretary
5 determines to be necessary to implement
6 this section.

7 “(ii) REPORTS TO CONGRESS.—For
8 fiscal year 2020 and each subsequent fiscal
9 year for which fees are collected under this
10 section, the Secretary shall, not later than
11 120 days after the end of the respective
12 fiscal year, submit to the Congress finan-
13 cial and performance reports with respect
14 to such fees.”.

15 (f) PROHIBITED ACT.—Section 301(q)(1)(B) of the
16 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
17 331(q)(1)(B)) is amended by inserting “919(b)(6)(B),”
18 before “or 920”.

19 **SEC. 106. REGULATION OF PRODUCTS CONTAINING ALTER-**
20 **NATIVE NICOTINE.**

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

24 (1) not later than 1 year after the date of en-
25 actment of this Act, issue an interim final rule pro-

1 viding for the regulation of products containing al-
2 ternative nicotine under the Federal Food, Drug,
3 and Cosmetic Act (21 U.S.C. 301 et seq.); and

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

7 (b) ALTERNATIVE NICOTINE.—In this section, the
8 term “alternative nicotine” means nicotine that is not
9 made or derived from tobacco plants and may include nic-
10 otine that is chemically synthesized, synthesized from re-
11 combinant genetic technology, or extracted from non-to-
12 bacco plants.

13 **SEC. 107. UPDATE TO YOUTH TOBACCO PREVENTION PUB-**
14 **LIC AWARENESS CAMPAIGNS.**

15 (a) IN GENERAL.—The Secretary of Health and
16 Human Services shall—

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

23 (2) as applicable, modify such campaigns to in-
24 clude awareness and education materials designed
25 for individuals who are 18 to 21 years of age.

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

5 **SEC. 108. EXEMPTION FROM PREMARKET REVIEW OF CER-**
6 **TAIN TOBACCO PRODUCTS.**

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

10 (1) in subparagraph (A)—

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

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

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

15 “(iii) subject to subparagraph (C), for
16 the period beginning on the date of the en-
17 actment of the Protecting American Lungs
18 and Reversing the Youth Tobacco Epi-
19 demic Act of 2020 and ending on Sep-
20 tember 30, 2028, the tobacco product is a
21 cigar and—

22 “(I) is wrapped in whole tobacco
23 leaf;

24 “(II) contains a 100-percent leaf
25 tobacco binder;

1 “(III) contains primarily long
2 filler tobacco;

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

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

7 “(VI) has no filter, tip, or non-
8 tobacco mouthpiece;

9 “(VII)(aa) is made by combining
10 manually the wrapper, filler, and
11 binder and is capped by hand; or

12 “(bb) has a homogenized tobacco
13 leaf binder and is made in the United
14 States using human hands to lay the
15 100-percent leaf tobacco binder onto
16 only one machine that bunches,
17 wraps, and caps each individual cigar;
18 and

19 “(VIII) has a retail price (after
20 discounts or coupons) per cigar of no
21 less than—

22 “(aa) for calendar years
23 2019 and 2020, \$12; and

24 “(bb) for each subsequent
25 calendar year, \$12 multiplied by

1 any percent increase in the Con-
2 sumer Price Index for all urban
3 consumers (all items; U.S. city
4 average) since calendar year
5 2020.”; and

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

7 “(C) DETERMINATION OF APPLICA-
8 BILITY.—

9 “(i) IN GENERAL.—The Secretary
10 shall, notwithstanding subparagraph
11 (A)(iii) or any determination of substantial
12 equivalence, if any of the conditions speci-
13 fied in clause (ii) are met—

14 “(I) withdraw any exemption ap-
15 plicable to a tobacco product or prod-
16 ucts described in such subparagraph;

17 “(II) require that applications for
18 review under this section be submitted
19 with respect to such product or prod-
20 ucts; and

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

1 “(ii) CONDITIONS.—The conditions
2 specified in this clause are that—

3 “(I) the Secretary determines
4 that the use of a tobacco product or
5 products described in subparagraph
6 (A)(iii) has resulted in an emerging
7 public health threat;

8 “(II) data from a National Youth
9 Tobacco Survey (or successor survey)
10 conducted after the date of the enact-
11 ment of the Protecting American
12 Lungs and Reversing the Youth To-
13 bacco Epidemic Act of 2020 identifies
14 a rise in youth usage of tobacco prod-
15 ucts described in section
16 910(a)(2)(A)(iii); or

17 “(III) the Secretary determines
18 that a tobacco product or products no
19 longer meets the criteria specified in
20 such subparagraph.”.

21 (b) NATIONAL ACADEMIES STUDY AND REPORT.—

22 (1) IN GENERAL.—The Secretary of Health and
23 Human Services, acting through the Commissioner
24 of Food and Drugs, shall enter into an agreement
25 with the National Academies of Sciences, Engineer-

1 ing, and Medicine under which the National Acad-
2 emies shall conduct a study on—

3 (A) the public health impact of having to-
4 bacco products described in subsection
5 (a)(2)(A)(iii) of section 910 of the Federal
6 Food, Drug, and Cosmetic Act (21 U.S.C.
7 387j), as amended by subsection (a), exempt
8 from premarket review under such section;

9 (B) the youth usage of such tobacco prod-
10 ucts; and

11 (C) the market share of such products.

12 (2) REPORT.—The agreement under paragraph
13 (1) shall include a requirement that the National
14 Academies of Sciences, Engineering, and Medicine
15 submit to Congress, not later than December 31,
16 2026, a report on the findings of the study con-
17 ducted under such paragraph.

18 **SEC. 109. PUBLIC EDUCATION.**

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

22 “(g) EDUCATION ON TOBACCO PRODUCTS.—

23 “(1) IN GENERAL.—Beginning not later than 6
24 months after the date of the enactment of the Pro-
25 tecting American Lungs and Reversing the Youth

1 Tobacco Epidemic Act of 2020, the Secretary of
2 Health and Human Services, acting through the
3 Commissioner of Food and Drugs and in consulta-
4 tion with the Surgeon General of the Public Health
5 Service, shall provide educational materials for
6 health care providers, members of the public, and
7 law enforcement officials, regarding—

8 “(A) the authority of the Food and Drug
9 Administration with respect to the regulation of
10 tobacco products (including enforcement of such
11 regulation);

12 “(B) the general processes of the Food and
13 Drug Administration for enforcing restrictions
14 on the manufacture and sale of tobacco prod-
15 ucts;

16 “(C) the general enforcement actions the
17 Food and Drug Administration may take to im-
18 plement the prohibition on characterizing fla-
19 vors in tobacco products under section
20 907(a)(1);

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

23 “(E) other information as the Secretary
24 determines appropriate.

1 “(2) CONTENT.—Educational materials pro-
2 vided under paragraph (1) may include—

3 “(A) explanations of key statutory and
4 regulatory terms, including the terms ‘tobacco
5 product’, ‘component parts’, ‘accessories’, ‘con-
6 stituent’, ‘additive’, ‘tobacco product manufac-
7 turer’, and ‘characterizing flavor’;

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

12 “(C) general educational information re-
13 lated to enforcement tools and processes used
14 by the Food and Drug Administration for viola-
15 tions of the prohibition specified in section
16 907(a)(1);

17 “(D) information on the health effects of
18 using tobacco products, including those with the
19 characterizing flavors referred to in section
20 907(a)(1); and

21 “(E) information on resources available re-
22 lated to smoking cessation.

23 “(3) FORMAT.—Educational materials provided
24 under paragraph (1) may be—

1 “(A) published in any format, including an
2 internet website, video, fact sheet, infographic,
3 webinar, or other format, as the Secretary de-
4 termines is appropriate and applicable; and

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

9 “(4) FUNDING.—To carry out this subsection,
10 there is authorized to be appropriated, and there is
11 appropriated, out of any funds in the Treasury not
12 otherwise appropriated, \$5,000,000 for each of fiscal
13 years 2021 through 2025. Funds made available by
14 the preceding sentence to carry out this subsection
15 shall be in addition to funds that are derived from
16 fees under section 919 and are otherwise made avail-
17 able to carry out this chapter.”.

18 **SEC. 110. REGULATIONS FOR RECORDKEEPING CON-**
19 **CERNING TRACKING AND TRACING.**

20 The Secretary of Health and Human Services, acting
21 through the Commissioner of Food and Drugs, shall pro-
22 mulgate the regulations required by section 920(b) of the
23 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 387t)
24 in accordance with the following schedule:

1 (1) Not later than 1 year after the date of en-
2 actment of this Act, the Secretary shall issue pro-
3 posed regulations.

4 (2) Not later than 2 years after the date of en-
5 actment of this Act, the Secretary shall promulgate
6 final regulations.

7 **TITLE II—FEDERAL TRADE**
8 **COMMISSION**

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

10 (a) ADVERTISING OF ELECTRONIC NICOTINE DELIV-
11 ERY SYSTEMS.—

12 (1) IN GENERAL.—It shall be unlawful—

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

17 (B) to market, advertise, promote, or en-
18 dorse, or to compensate any person for the
19 marketing, advertising, promotion, or endorse-
20 ment of, any electronic nicotine delivery system
21 without clearly disclosing that the communica-
22 tion is an advertisement, unless the communica-
23 tion is unambiguously identifiable as an adver-
24 tisement.

25 (2) ENFORCEMENT BY COMMISSION.—

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

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

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

20 (A) IN GENERAL.—If the attorney general
21 of a State has reason to believe a violation of
22 paragraph (1) has occurred or is occurring, the
23 attorney general, in addition to any authority
24 the attorney general may have to bring an ac-
25 tion in State court under the law of the State,

1 may bring a civil action in any court of com-
2 petent jurisdiction to—

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

5 (ii) enforce compliance with such
6 paragraph;

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

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

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

1 (C) AUTHORITY OF FEDERAL TRADE COM-
2 MISSION.—

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

7 (I) to intervene in the action;

8 (II) upon so intervening, to be
9 heard on all matters arising therein;
10 and

11 (III) to file petitions for appeal.

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

24 (D) RELATIONSHIP WITH STATE-LAW
25 CLAIMS.—

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

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

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

24 (4) RULEMAKING AUTHORITY.—The Commis-
25 sion may promulgate regulations under section 553

1 of title 5, United States Code, to implement para-
2 graph (1).

3 (b) REPORT TO CONGRESS ON TOBACCO PRODUCT
4 ADVERTISING.—

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

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

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

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

21 (A) Cigarettes.

22 (B) Cigars.

23 (C) Smokeless tobacco.

24 (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 SYS-
16 TEM.—The term “electronic nicotine delivery sys-
17 tem” means a tobacco product that is an electronic
18 device that delivers nicotine, flavor, or another sub-
19 stance via an aerosolized solution to the user inhal-
20 ing from the device (including e-cigarettes, e-hookah,
21 e-cigars, vape pens, advanced refillable personal va-
22 porizers, and electronic pipes) and any component,
23 liquid, part, or accessory of such a device, whether
24 or not sold separately.

1 (5) ENDORSE.—The term “endorse” means to
2 communicate an advertising message (including a
3 verbal statement, demonstration, or depiction of the
4 name, signature, likeness, or other identifying per-
5 sonal characteristics of an individual or the name or
6 seal of an organization) that consumers are likely to
7 believe reflects the opinions, beliefs, findings, or ex-
8 periences of a party other than the sponsoring ad-
9 vertiser, even if the views expressed by such party
10 are identical to those of the sponsoring advertiser.

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

14 (7) SMOKELESS TOBACCO.—The term “smoke-
15 less tobacco” has the meaning given such term in
16 section 900 of the Federal Food, Drug, and Cos-
17 metic Act (21 U.S.C. 387).

18 (8) TOBACCO PRODUCT.—The term “tobacco
19 product” has the meaning given such term in section
20 201 of the Federal Food, Drug, and Cosmetic Act
21 (21 U.S.C. 321).

1 **TITLE III—PUBLIC HEALTH**
2 **PROGRAMS**

3 **SEC. 301. OUTREACH TO MEDICALLY UNDERSERVED COM-**
4 **MUNITIES.**

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

7 (1) in subsection (b)—

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

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

12 “(4) to educate and provide guidance to medi-
13 cally underserved communities, particularly racial
14 and ethnic minority populations, regarding effective
15 evidence-based strategies—

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

18 “(B) for smoking cessation, including ces-
19 sation of the use of menthol-flavored tobacco
20 products, and the cessation of the use of e-ciga-
21 rettes and electronic nicotine delivery systems;”;

22 (2) in subsection (d)(1)(B), by inserting “, in-
23 cluding chronic diseases related to and caused by to-
24 bacco use” after “diseases”; and

1 (3) in subsection (j), by striking “are author-
2 ized to be appropriated, such sums as may be nec-
3 essary to carry out this section for each of fiscal
4 years 2010 through 2014” and inserting “is author-
5 ized to be appropriated, and there is appropriated,
6 out of any funds in the Treasury not otherwise ap-
7 propriated, \$75,000,000 to carry out this section for
8 each of fiscal years 2021 through 2025”.

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

12 Part B of title III of the Public Health Service Act
13 (42 U.S.C. 243 et seq.) is amended by inserting after sec-
14 tion 317U (42 U.S.C. 247b–23) the following:

15 **“SEC. 317V. DEMONSTRATION GRANT PROGRAM TO DE-**
16 **VELOP STRATEGIES FOR SMOKING CES-**
17 **SATION IN MEDICALLY UNDERSERVED COM-**
18 **MUNITIES.**

19 “(a) IN GENERAL.—The Secretary, acting through
20 the Director of the Centers for Disease Control and Pre-
21 vention, shall establish a demonstration program to award
22 grants to, or contract with, State, local, or Tribal public
23 health departments to support—

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

1 cessation of the use of menthol-flavored tobacco
2 products, and the cessation of the use of e-cigarettes
3 and electronic nicotine delivery systems, for popu-
4 lations in medically underserved communities, par-
5 ticularly racial and ethnic minority populations;

6 “(2) the development of improved communica-
7 tion and outreach tools to reach populations in medi-
8 cally underserved communities, particularly racial
9 and ethnic minority populations, addicted to tobacco
10 products, including e-cigarettes and menthol-flavored
11 tobacco products; and

12 “(3) improved coordination, access, and refer-
13 rals to services for tobacco cessation and the ces-
14 sation of the use of e-cigarettes and electronic nico-
15 tine delivery systems, including tobacco cessation
16 products approved by the Food and Drug Adminis-
17 tration and mental health and counseling services.

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

23 “(c) AUTHORIZATION OF APPROPRIATIONS.—To
24 carry out this section, there is authorized to be appro-
25 priated, and there is appropriated, out of any funds in

1 the Treasury not otherwise appropriated, \$75,000,000 for
2 each of fiscal years 2021 through 2025.”.

3 **SEC. 303. PUBLIC AWARENESS, EDUCATION, AND PREVEN-**
4 **TION CAMPAIGN.**

5 Part B of title III of the Public Health Service Act
6 (42 U.S.C. 243 et seq.), as amended by section 302, is
7 further amended by inserting after section 317V the fol-
8 lowing new section:

9 **“SEC. 317W. PUBLIC AWARENESS, EDUCATION, AND PRE-**
10 **VENTION CAMPAIGN REGARDING TOBACCO.**

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

19 “(b) REQUIREMENTS.—The campaign under this sec-
20 tion shall—

21 “(1) be an evidence-based media and public en-
22 gagement initiative;

23 “(2) be carried out through competitively bid
24 contracts;

1 “(3) include the development of culturally and
2 linguistically competent resources that may be tai-
3 lored for communities with high rates of youth to-
4 bacco use;

5 “(4) be complementary to, and coordinated
6 with, any other Federal efforts; and

7 “(5) include message testing to identify cul-
8 turally and linguistically competent and effective
9 messages for behavioral change.

10 “(c) OPTIONAL COMPONENTS.—The campaign under
11 this section may include—

12 “(1) the use of—

13 “(A) television, radio, print, the internet,
14 and other commercial marketing venues; and

15 “(B) in-person public communications; and

16 “(2) the award of grants to State, local, and
17 Tribal public health departments to encourage part-
18 nerships with community organizations and health
19 care providers to develop and deliver evidence-based
20 strategies to prevent youth tobacco use.

21 “(d) FUNDING.—To carry out this section, there is
22 authorized to be appropriated, and there is appropriated,
23 out of any funds in the Treasury not otherwise appro-
24 priated, \$45,000,000 for each of fiscal years 2021 through
25 2025.”.

1 **SEC. 304. TOBACCO CESSATION TREATMENT GRANTS TO**
2 **HEALTH CENTERS.**

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

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

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

9 “(k) TOBACCO CESSATION GRANTS.—

10 “(1) IN GENERAL.—The Secretary may award
11 grants to health centers to provide comprehensive to-
12 bacco cessation treatment, including counseling and
13 tobacco cessation therapies.

14 “(2) FUNDING.—For the purpose of carrying
15 out this subsection, in addition to other amounts
16 available for such purpose, there is authorized to be
17 appropriated, and there is appropriated, out of funds
18 in the Treasury not otherwise appropriated,
19 \$125,000,000 for each of fiscal years 2021 through
20 2025.”.

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

23 (1) in subsection (e)(3)(B), by striking
24 “(k)(3)(J)” and inserting “(l)(3)(J)”;

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

1 (3) in subsection (l)(3)(H), as redesignated, by
2 striking “or (p)” and inserting “or (q)”;

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

4 (A) by striking “(k)(3)” and inserting
5 “(l)(3)”; and

6 (B) by striking “(m)” and inserting “(n)”;

7 (5) in subsection (q), as redesignated, by strik-
8 ing “(k)(3)(G)” and inserting “(l)(3)(G)”;

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

10 (A) by striking “(k)(3)” and inserting
11 “(l)(3)”; and

12 (B) by striking “(k)(3)(H)” and inserting
13 “(l)(3)(H)”; and

14 (7) in subsection (s)(3)(I), as redesignated, by
15 striking “(q)(4)” and inserting “(r)(4)”.

16 (c) TECHNICAL CORRECTIONS.—

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

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

1 **SEC. 305. GRANTS FOR RESEARCH.**

2 Part P of title III of the Public Health Service Act
3 (42 U.S.C. 280g et seq.) is amended by adding at the end
4 the following new section:

5 **“SEC. 399V-7. GRANTS FOR RESEARCH ON PREVENTION,**
6 **AND CESSATION, OF THE USE OF TOBACCO**
7 **PRODUCTS.**

8 “(a) IN GENERAL.—The Secretary shall award
9 grants to support—

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

13 “(A) cessation of the use of flavored com-
14 bustible cigarettes, including menthol-flavored
15 cigarettes;

16 “(B) cessation of the use of e-cigarette
17 products; and

18 “(C) prevention and cessation strategies
19 targeted toward youth; and

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

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

1 priated, \$75,000,000 for each of fiscal years 2021 through
2 2025.”.

3 **TITLE IV—NICOTINE OR VAPING**
4 **ACCESS PROTECTION AND**
5 **ENFORCEMENT**

6 **SEC. 401. INCREASING CIVIL PENALTIES APPLICABLE TO**
7 **CERTAIN VIOLATIONS OF RESTRICTIONS ON**
8 **SALE AND DISTRIBUTION OF TOBACCO PROD-**
9 **UCTS.**

10 (a) PENALTIES.—Subparagraph (A) of section
11 103(q)(2) of the Family Smoking Prevention and Tobacco
12 Control Act (21 U.S.C. 333 note) is amended to read as
13 follows:

14 “(A) IN GENERAL.—The amount of the
15 civil penalty to be applied for violations of re-
16 strictions promulgated under section 906(d), as
17 described in paragraph (1), shall be as follows:

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

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

1 “(II) in the case of a second vio-
2 lation within a 12-month period,
3 \$500;

4 “(III) in the case of a third viola-
5 tion within a 24-month period,
6 \$1,000;

7 “(IV) in the case of a fourth vio-
8 lation within a 24-month period,
9 \$4,000;

10 “(V) in the case of a fifth viola-
11 tion within a 36-month period,
12 \$10,000; and

13 “(VI) in the case of a sixth or
14 subsequent violation within a 48-
15 month period, \$20,000 as determined
16 by the Secretary on a case-by-case
17 basis.

18 “(ii) With respect to a retailer that
19 does not have an approved training pro-
20 gram, the amount of the civil penalty shall
21 not exceed—

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

1 “(II) in the case of a second vio-
2 lation within a 12-month period,
3 \$1,000;

4 “(III) in the case of a third viola-
5 tion within a 24-month period,
6 \$2,000;

7 “(IV) in the case of a fourth vio-
8 lation within a 24-month period,
9 \$4,000;

10 “(V) in the case of a fifth viola-
11 tion within a 36-month period,
12 \$10,000; and

13 “(VI) in the case of a sixth or
14 subsequent violation within a 48-
15 month period, \$20,000 as determined
16 by the Secretary on a case-by-case
17 basis.”.

18 (b) APPLICABILITY.—The amendment made by sub-
19 section (a) applies with respect to a violation of a restric-
20 tion promulgated under section 906(d)(1) of the Federal
21 Food, Drug, and Cosmetic Act (21 U.S.C. 387f(d)(1)), as
22 described in section 103(q)(1) of the Family Smoking Pre-
23 vention and Tobacco Control Act (21 U.S.C. 333 note),
24 occurring on or after the day that is 6 months after the
25 date of enactment of this Act. The penalties specified in

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

6 **SEC. 402. STUDY AND REPORT ON E-CIGARETTES.**

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

10 (1) complete a study on—

11 (A) the relationship of e-cigarettes to to-
12 bacco cessation;

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

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

17 (2) submit to the Congress a report on the re-
18 sults of such study, including recommendations
19 based on such results.

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

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

24 (a) IN GENERAL.—Section 5701 of the Internal Rev-
25 enue Code of 1986 is amended by redesignating subsection

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

3 “(h) NICOTINE.—On taxable nicotine, manufactured
4 in or imported into the United States, there shall be im-
5 posed a tax equal to the dollar amount specified in section
6 5701(b)(1) (or, if greater, \$50.33) per 1,810 milligrams
7 of nicotine (and a proportionate tax at the like rate on
8 any fractional part thereof).”.

9 (b) TAXABLE NICOTINE.—Section 5702 of such Code
10 is amended by adding at the end the following new sub-
11 section:

12 “(q) TAXABLE NICOTINE.—

13 “(1) IN GENERAL.—Except as otherwise pro-
14 vided in this subsection, the term ‘taxable nicotine’
15 means any nicotine which has been extracted, con-
16 centrated, or synthesized.

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

23 “(A) a drug—

24 “(i) that is approved under section
25 505 of the Federal Food, Drug, and Cos-

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

3 “(ii) for which an investigational use
4 exemption has been authorized under sec-
5 tion 505(i) of the Federal Food, Drug, and
6 Cosmetic Act or under section 351(a) of
7 the Public Health Service Act; or

8 “(B) a combination product (as described
9 in section 503(g) of the Federal Food, Drug,
10 and Cosmetic Act), the constituent parts of
11 which were approved or cleared under section
12 505, 510(k), or 515 of such Act.

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

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

1 (d) MANUFACTURER OF TAXABLE NICOTINE.—Sec-
2 tion 5702 of such Code, as amended by subsection (b),
3 is further amended by adding at the end the following new
4 subsection:

5 “(r) MANUFACTURER OF TAXABLE NICOTINE.—

6 “(1) IN GENERAL.—Any person who extracts,
7 concentrates, or synthesizes nicotine shall be treated
8 as a manufacturer of taxable nicotine (and as manu-
9 facturing such taxable nicotine).

10 “(2) APPLICATION OF RULES RELATED TO
11 MANUFACTURERS OF TOBACCO PRODUCTS.—Any
12 reference to a manufacturer of tobacco products, or
13 to manufacturing tobacco products, shall be treated
14 as including a reference to a manufacturer of tax-
15 able nicotine, or to manufacturing taxable nicotine,
16 respectively.”.

17 (e) EFFECTIVE DATE.—

18 (1) IN GENERAL.—The amendments made by
19 this section shall apply to articles manufactured or
20 imported in calendar quarters beginning more than
21 90 days after the date of the enactment of this Act.

22 (2) TRANSITION RULE FOR PERMIT AND BOND
23 REQUIREMENTS.—A person which is lawfully en-
24 gaged in business as a manufacturer or importer of
25 taxable nicotine (within the meaning of subchapter

1 A of chapter 52 of the Internal Revenue Code of
2 1986, as amended by this section) on the date of the
3 enactment of this Act, first becomes subject to the
4 requirements of subchapter B of chapter 52 of such
5 Code by reason of the amendments made by this
6 section, and submits an application under such sub-
7 chapter B to engage in such business not later than
8 90 days after the date of the enactment of this Act,
9 shall not be denied the right to carry on such busi-
10 ness by reason of such requirements before final ac-
11 tion on such application.

12 **TITLE VI—FURTHER HEALTH** 13 **INVESTMENTS**

14 **SEC. 601. WAIVING MEDICARE COINSURANCE FOR** 15 **COLORECTAL CANCER SCREENING TESTS.**

16 Section 1833(a) of the Social Security Act (42 U.S.C.
17 1395l(a)) is amended—

18 (1) in the second sentence, by striking “section
19 1834(0)” and inserting “section 1834(o)”;

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

22 (3) by inserting the following third sentence fol-
23 lowing such second sentence: “For services furnished
24 on or after January 1, 2024, paragraph (1)(Y) shall
25 apply with respect to a colorectal cancer screening

1 test regardless of the code that is billed for the es-
2 tablishment of a diagnosis as a result of the test, or
3 for the removal of tissue or other matter or other
4 procedure that is furnished in connection with, as a
5 result of, and in the same clinical encounter as the
6 screening test.”.

7 **SEC. 602. SAFE HARBOR FOR HIGH DEDUCTIBLE HEALTH**
8 **PLANS WITHOUT DEDUCTIBLE FOR CERTAIN**
9 **INHALERS.**

10 (a) IN GENERAL.—Section 223(c)(2)(C) of the Inter-
11 nal Revenue Code of 1986 is amended—

12 (1) by striking “for preventive care” and insert-
13 ing “for one or more of the following:

14 “(i) Preventive care”, and

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

17 “(ii) Inhalers or nebulizers for treat-
18 ment of any chronic lung disease (and any
19 medicine or drug which is delivered
20 through such inhaler or nebulizer for treat-
21 ment of such disease).”.

22 (b) CONFORMING AMENDMENT.—The heading for
23 section 223(c)(2)(C) of such Code is amended by striking
24 “PREVENTIVE CARE DEDUCTIBLE” and inserting “CER-
25 TAIN DEDUCTIBLES”.

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

Passed the House of Representatives February 28,
2020.

Attest:

Clerk.

116TH CONGRESS
2^D SESSION

H. R. 2339

AN ACT

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