

116TH CONGRESS
1ST SESSION

H. R. 2339

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

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

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
5 Tobacco 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. Fees applicable to all tobacco products.
 Sec. 105. Regulation of products containing synthetic nicotine.

TITLE II—FEDERAL TRADE COMMISSION

- Sec. 201. Advertising of tobacco products.

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

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

4 (a) ISSUANCE DEADLINES.—Not later than 12
 5 months after the date of enactment of this Act, the Sec-
 6 retary of Health and Human Services, acting through the
 7 Commissioner of Food and Drugs, shall publish a final
 8 rule pursuant to section 4(d) of the Federal Cigarette La-
 9 beling and Advertising Act (15 U.S.C. 1333(d)).

10 (b) CONFORMING CHANGE.—Section 4(d) of the Fed-
 11 eral Cigarette Labeling and Advertising Act (15 U.S.C.
 12 1333(d)) is amended by striking “Not later than 24
 13 months after the date of enactment of the Family Smok-
 14 ing Prevention and Tobacco Control Act, the Secretary”
 15 and inserting “The Secretary”.

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

18 (a) IN GENERAL.—Not later than 1 year after the
 19 date of enactment of this Act, the Secretary of Health and
 20 Human Services, acting through the Commissioner of
 21 Food and Drugs, shall promulgate a final rule amending

1 part 1140 of subchapter K of title 21, Code of Federal
2 Regulations—

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

9 (2) to make such changes as may be necessary
10 for consistency with the amendments made by sec-
11 tion 103 of this Act.

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

15 **SEC. 103. REDUCING CHILD AND ADOLESCENT NICOTINE**
16 **ADDICTION.**

17 (a) APPLICABILITY TO ALL TOBACCO PRODUCTS.—

18 (1) IN GENERAL.—Subsection (b) of section
19 901 of the Federal Food, Drug, and Cosmetic Act
20 (21 U.S.C. 387a) is amended to read as follows:

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

23 (2) RULE OF CONSTRUCTION.—Paragraph (1)
24 and the amendment made thereby shall not be con-
25 strued to limit the applicability of chapter IX of the

1 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
2 387a et seq.) to—

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

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

10 (b) MINIMUM AGE RESTRICTIONS.—Section 906(d)
11 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
12 387f(d)) is amended by striking paragraph (3) and insert-
13 ing the following:

14 “(3) MINIMUM AGE RESTRICTIONS.—

15 “(A) RESTRICTION.—It shall be unlawful
16 for any retailer, manufacturer, distributor,
17 third-party marketplace, or any other commer-
18 cial entity to sell a tobacco product to any per-
19 son younger than 21 years of age.

20 “(B) AGE VERIFICATION.—To ensure com-
21 pliance with subparagraph (A), a retailer shall,
22 at a minimum, verify by means of a govern-
23 ment-issued photographic identification the age
24 of the individual purchasing the product as pre-
25 scribed in—

1 “(i) subpart B of part 1140 of sub-
2 chapter K of title 21, Code of Federal Reg-
3 ulations; and

4 “(ii) successor regulations, including
5 the regulation required by section 102 of
6 the Reversing the Youth Tobacco Epidemic
7 Act of 2019 and any applicable regulation
8 imposing restrictions pursuant to para-
9 graph (1).

10 “(C) NON-PREEMPTION.—Subparagraphs
11 (A) and (B) shall not be construed to limit the
12 authority of a State or political subdivision of
13 a State, or the government of an Indian tribe,
14 as such authority is described in section 916.

15 “(D) REGULATIONS.—Not later than 180
16 days after the date of enactment of the Revers-
17 ing the Youth Tobacco Epidemic Act of 2019,
18 the Secretary shall promulgate a final regula-
19 tion to implement and enforce subparagraphs
20 (A) and (B).

21 “(E) TIMING.—Subparagraphs (A) and
22 (B) shall take effect on the date that is 180
23 days after the date of enactment of the Revers-
24 ing the Youth Tobacco Epidemic Act of 2019,
25 regardless of whether the Secretary has promul-

1 gated the final regulations required by subpara-
2 graph (D).”.

3 (c) PROHIBITION AGAINST REMOTE RETAIL
4 SALES.—Paragraph (4) of section 906(d) of the Federal
5 Food, Drug, and Cosmetic Act (21 U.S.C. 387f(d)) is
6 amended to read as follows:

7 “(4) PROHIBITION AGAINST REMOTE RETAIL
8 SALES.—Not later than 2 years after the date of en-
9 actment of the Reversing the Youth Tobacco Epi-
10 demic Act of 2019, the Secretary shall promulgate
11 a final regulation under paragraph (1) prohibiting
12 the retail sale of all tobacco products, including elec-
13 tronic nicotine delivery systems and electronic nico-
14 tine delivery system accessories, other than retail
15 sales through a direct, face-to-face exchange between
16 a retailer and a consumer.”.

17 (d) PROHIBITING FLAVORING OF TOBACCO PROD-
18 UCTS.—

19 (1) PROHIBITION.—Subparagraph (A) of sec-
20 tion 907(a)(1) of the Federal Food, Drug, and Cos-
21 metic Act (21 U.S.C. 387g(a)(1)) is amended to
22 read as follows:

23 “(A) SPECIAL RULE.—Beginning on the
24 date that is 1 year after the date of enactment
25 of the Reversing the Youth Tobacco Epidemic

1 Act of 2019, except as provided in subpara-
2 graph (C), a tobacco product or any of its com-
3 ponent parts or accessories (including the to-
4 bacco, filter, or paper) shall not contain, as a
5 constituent (including a smoke constituent) or
6 additive, an artificial or natural flavor (other
7 than tobacco) that is a characterizing flavor of
8 the tobacco product or tobacco smoke or an
9 herb or spice, including menthol, mint, straw-
10 berry, grape, orange, clove, cinnamon, pine-
11 apple, vanilla, coconut, licorice, cocoa, chocolate,
12 cherry, or coffee. Nothing in this subparagraph
13 shall be construed to limit the Secretary’s au-
14 thority to take action under this section or
15 other sections of this Act applicable to any arti-
16 ficial or natural flavor, herb, or spice.”.

17 (2) EXCEPTION.—Paragraph (1) of section
18 907(a) of the Federal Food, Drug, and Cosmetic Act
19 (21 U.S.C. 387g(a)) is amended by adding at the
20 end the following new subparagraph:

21 “(C) EXCEPTION FOR CHARACTERIZING
22 FLAVORS TO DECREASE SMOKING.—Notwith-
23 standing subparagraph (A), an electronic nico-
24 tine delivery system product or any component
25 or part of such a product may contain, as a

1 constituent (including a smoke constituent) or
2 additive, an artificial or natural flavor or an
3 herb or spice, that is a characterizing flavor of
4 the tobacco product or tobacco smoke so long as
5 the Secretary, in coordination with the Commis-
6 sioner of Food and Drugs, determines that such
7 characterizing flavor will be appropriate for the
8 protection of public health because it—

9 “(i) will significantly increase the like-
10 lihood of smoking cessation among current
11 users of tobacco products;

12 “(ii) will not increase the likelihood
13 that individuals who do not use tobacco
14 products, including youth, will start using
15 such products; and

16 “(iii) will not increase the likelihood of
17 harm to the person using the product.”.

18 (3) SAVINGS PROVISION.—Section 907(a)(1) of
19 the Federal Food, Drug, and Cosmetic Act (21
20 U.S.C. 387g(a)(1)), as in effect on the date of enact-
21 ment of this Act, shall remain in effect until the
22 amendments made to such section 907(a)(1) by this
23 subsection take effect.

1 **SEC. 104. FEES APPLICABLE TO ALL TOBACCO PRODUCTS.**

2 (a) INCREASE IN TOTAL AMOUNT.—Section
3 919(b)(1)(K) of the Federal Food, Drug, and Cosmetic
4 Act (21 U.S.C. 387s(b)(1)(K)) is amended by striking
5 “\$712,000,000” and inserting “\$812,000,000”.

6 (b) APPLICATION OF USER FEES TO ALL CLASSES
7 OF TOBACCO PRODUCTS.—Paragraph (2) of section
8 919(b) of the Federal Food, Drug, and Cosmetic Act (21
9 U.S.C. 387s(b)(2)) is amended to read as follows:

10 “(2) ALLOCATIONS OF ASSESSMENT BY CLASS
11 OF TOBACCO PRODUCTS.—The total user fees as-
12 sessed and collected under subsection (a) each fiscal
13 year with respect to each class of tobacco products
14 shall be an amount that is determined pursuant to
15 a formula developed by the Secretary. Such formula
16 shall ensure that the amount of fees collected is in-
17 creased by the total percentage change that occurred
18 in the Consumer Price Index for all urban con-
19 sumers (all items; United States city average) for
20 the 12-month period ending June 30 preceding the
21 fiscal year.”.

22 (c) ALLOCATION OF ASSESSMENT WITHIN EACH
23 CLASS OF TOBACCO PRODUCT.—Section 919(b)(4) of the
24 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
25 387s(b)(4)) is amended by striking “shall be the percent-
26 age determined for purposes of allocations under sub-

1 sections (e) through (h) of section 625 of Public Law 108–
2 357” and inserting “shall be the percentage determined
3 by the Secretary”.

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

7 (1) by striking paragraphs (5) and (7); and

8 (2) by redesignating paragraph (6) as para-
9 graph (5).

10 (e) APPLICABILITY.—The amendments made by this
11 section apply beginning with fiscal year 2022. Section 919
12 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
13 387s), as in effect on the day before the date of enactment
14 of this Act, shall apply with respect to fiscal years pre-
15 ceding fiscal year 2022.

16 **SEC. 105. REGULATION OF PRODUCTS CONTAINING SYN-**
17 **THETIC NICOTINE.**

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

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

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

4 (b) **SYNTHETIC NICOTINE DEFINED.**—In this sec-
5 tion, the term “synthetic nicotine” means nicotine that is
6 not made or derived from tobacco.

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 any roll
6 of tobacco wrapped in leaf tobacco or in any sub-
7 stance containing tobacco (other than any roll of to-
8 bacco which is a cigarette within the meaning of
9 paragraph (2)).

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.—

17 (A) IN GENERAL.—The term “electronic
18 nicotine delivery system” means—

19 (i) an electronic device that—

20 (I) converts a mixture containing
21 nicotine or other substances into an
22 aerosol to be inhaled by the user; and

23 (II) is a tobacco product; or

24 (ii) a mixture that—

1 (I) contains nicotine or other
2 substances that can be aerosolized
3 and inhaled by the user; and

4 (II) is a tobacco product.

5 (B) EXCLUSION.—The term “electronic
6 nicotine delivery system” does not include any
7 product that—

8 (i) has been approved or otherwise au-
9 thorized by the Food and Drug Adminis-
10 tration for the purpose of sale as a tobacco
11 cessation product or for other therapeutic
12 purposes; and

13 (ii) is marketed and sold solely for
14 such purpose or purposes.

15 (5) ENDORSE.—The term “endorse” means to
16 communicate an advertising message (including a
17 verbal statement, demonstration, or depiction of the
18 name, signature, likeness, or other identifying per-
19 sonal characteristics of an individual or the name or
20 seal of an organization) that consumers are likely to
21 believe reflects the opinions, beliefs, findings, or ex-
22 periences of a party other than the sponsoring ad-
23 vertiser, even if the views expressed by such party
24 are identical to those of the sponsoring advertiser.

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

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

8 (8) TOBACCO PRODUCT.—The term “tobacco
9 product” has the meaning given such term in section
10 201 of the Federal Food, Drug, and Cosmetic Act
11 (21 U.S.C. 321).

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