AMENDMENT TO COMMITTEE PRINT OF H.R. 2339

OFFERED BY

Page 6, line 22, through page 7, line 10, strike subsection (c) (and make such conforming changes as may be necessary).

Page 8, line 24, after ''possession'' insert '', nor shall it be used as a justification to stop, search, or conduct any other investigative measure against any individual''.

Page 12, after line 4, insert after section 103 the following new section (and make such other conforming changes as may be necessary):

SEC. 104. PROHIBITION AGAINST REMOTE RETAIL SALES.

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

''(4) PROHIBITION AGAINST REMOTE RETAIL SALES.—

''(A) PROHIBITION.—Not later than 18 months after the date of enactment of the the Reversing the Youth Tobacco Epidemic Act of 2019, the Secretary shall promulgate a final

regulation prohibiting the retail sale of all tobacco products other than retail sales through a direct, face-to-face exchange between a retailer and a consumer.

''(B) EXCEPTION FOR CERTAIN CIGAR TOBACCO PRODUCTS.—

''(i) EXCEPTION.—The regulation required by subparagraph (A) shall not apply to tobacco products described in section 910(a)(2)(A)(iii).

''(ii) APPLICABLE REQUIREMENTS.—Not later than 18 months after the date of enactment of the the Reversing the Youth Tobacco Epidemic Act of 2019, the Secretary shall promulgate regulations regarding the sale and distribution of tobacco products described in section 910(a)(2)(A)(iii) that occur through means other than a direct, face-to-face exchange between a retailer and a consumer in order to prevent the sale and distribution of tobacco products described in section 910(a)(2)(A)(iii) to individuals who have not attained the minimum age established by applicable law for the purchase of such

products, including requirements for age verification.

''(C) RELATION TO OTHER AUTHORITY.—Nothing in this paragraph—

''(i) limits the authority of the Secretary to take additional actions under the other paragraphs of this subsection; or

''(ii) preempts the authority of a State or local government to establish restrictions on the retail sale of tobacco products that are at least as restrictive as the prohibition under subparagraph (A).''.

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

Page 12, line 20, through page 13, line 5, amend subsection (b) to read as follows:

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

(1) IN GENERAL.—Subparagraph (A) of section 919(b)(2) of the Federal Food Drug, and Cosmetic

Act (21 U.S.C. 387s(b)(2)) is amended to read as follows:

''(A) IN GENERAL.—

''(i) FISCAL YEARS 2020 AND 2021.—For fiscal years 2020 and 2021, user fees shall be assessed and collected under subsection (a) only with respect to the classes of tobacco products listed in subparagraph (B)(i), and the total such user fees with respect to each such class shall be an amount that is equal to the applicable percentage of each such class for the fiscal year multiplied by the amount specified in paragraph (1) for the fiscal year.

''(ii) SUBSEQUENT FISCAL YEARS.—For fiscal year 2022 and each subsequent fiscal year, user fees shall be assessed and collected under subsection (a) with respect to each class of tobacco products to which this chapter applies (including tobacco products that the Secretary by regulation deems to be subject to this chapter), and the total user fees with respect to each such class shall be—

''(I) with respect to each class of tobacco products listed in subparagraph (B)(i), an amount that is calculated in the same way as the amounts calculated for fiscal years 2020 and 2021 under clause (i), except that for purposes of fiscal years 2022 and subsequent fiscal years, instead of multiplying the applicable percentage of each such class by 'the amount specified in paragraph (1) for the fiscal year', the applicable percentage shall be multiplied by—

''(aa) the amount specified in paragraph (1) for the fiscal year, reduced by

''(bb) the total user fees assessed and collected pursuant to subclause (II) for the fiscal year; and

''(II) with respect to each class of tobacco products to which this chapter applies but which is not listed in subparagraph (B)(i), an amount deter-

mined pursuant to a formula under subparagraph (C).''.

(2) OTHER TOBACCO PRODUCTS.—Section 919(b)(2) of the Federal Food Drug, and Cosmetic Act (21 U.S.C. 387s(b)(2)), as amended by paragraph (1), is further amended by adding at the end the following new subparagraphs:

''(C) ALLOCATION FOR OTHER TOBACCO PRODUCTS.—

''(i) IN GENERAL.—Beginning with fiscal year 2022, the total user fees assessed and collected under subsection (a) each fiscal year with respect to each class of tobacco products not listed in subparagraph (B)(i) shall be an amount that is determined pursuant to a formula developed by the Secretary by regulation using information required to be submitted under subparagraph (D).

''(ii) ALLOCATION FOR OTHER TOBACCO PRODUCTS.—For each class of tobacco products not listed in subparagraph (B)(i), the percentage of fees under the formula under clause (i) for the respective fiscal year shall be equal to the percentage

of the gross domestic sales in the previous calendar year that is attributable to such class of tobacco products in such calendar year, as determined by the Secretary.

''(iii) ALLOCATION OF ASSESSMENT WITHIN EACH CLASS OF OTHER TOBACCO PRODUCTS.—The percentage of the total user fee to be paid by each manufacturer or importer of tobacco products in a class not listed in subparagraph (B)(i) shall be determined by the Secretary, based on the percentage of the gross domestics sales of all such classes of tobacco products by all manufacturers and importers in the previous calendar year that is attributable to such manufacturer or importer.

''(iv) EFFECT OF FAILURE TO FINALIZE FORMULA ON TIME.—If the Secretary for any reason fails to finalize by fiscal year 2022 the formula required by this subparagraph for the assessment and collection of user fees for classes of tobacco products not listed in subparagraph (B)(i)—

''(I) the Secretary shall continue to assess and collect fees under subsection (a) with respect to each class of tobacco products listed in subparagraph (B)(i); and

''(II) until the first fiscal year commencing after the finalization of such formula, the exception described in subparagraph (A)(ii)(I) shall not apply.

''(v) REVISIONS BY REGULATION.—Any revisions to the formula promulgated pursuant to this subparagraph shall be by regulation.

''(vi) DEFINITION.—In this subparagraph, the term 'gross domestic sales' means the total value in dollars of the sale or distribution by manufacturers and importers of tobacco products in the United States in classes not listed in subparagraph (B)(i), as determined based on the aggregation of sales data from every manufacturer and importer of tobacco products that submits sales data to the Secretary.

''(D) INFORMATION REQUIRED TO BE SUBMITTED.—Each manufacturer or importer of any tobacco product shall submit to the Secretary the information required under this subparagraph by March 1, 2021, for calendar year 2020, by April 1, 2021, for the period of January 1, 2021, through March 30, 2021, and monthly thereafter. Such information shall include—

''(i) the identification of the manufacturer or importer;

''(ii) the class or classes of tobacco products sold by the manufacturer or importer;

''(iii) the full listing of the finished tobacco products in a class not listed in subparagraph (B)(i) sold or distributed by the manufacturer or importer in the United States; and

''(iv) the gross domestic sales data for each class of finished tobacco products sold or distributed by the manufacturer or importer in the United States.''.

(3) PROHIBITED ACT.—Section 301(q)(1)(B) of the Federal Food, Drug, and Cosmetic Act (21

U.S.C. 331(q)(1)(B)) is amended by inserting ''919(b)(2)(D),'' before ''or 920''.

Page 13, line 19, strike ''(7) and (8)'' and insert ''(5) and (6)''.

Page 16, after line 9, add at the end of title I the following (and make such conforming changes as may be necessary):

SEC. 108. EXEMPTION FROM PREMARKET APPROVAL OF CERTAIN TOBACCO PRODUCTS.

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

(1) in subparagraph (A)—

(A) in clause (i)(II), by striking ''or'';

(B) in clause (ii), by striking the period at the end and inserting ''; or''; and

(C) by adding at the end the following:

''(iii) subject to subparagraph (C), for the period beginning on the date of the enactment of the Reversing the Youth Tobacco Epidemic Act of 2019 and ending on September 30, 2028, the tobacco product is a cigar and—

''(I) is wrapped in whole tobacco leaf;

''(II) contains a 100-percent leaf tobacco binder;

''(III) contains primarily long filler tobacco;

''(IV) does not have a characterizing flavor other than tobacco;

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

''(VI) has no filter, tip, or non-tobacco mouthpiece;

''(VII)(aa) is made by combining manually the wrapper, filler, and binder and is capped by hand; or

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

''(VIII) has a retail price (after discounts or coupons) per cigar of no less than—

''(aa) for calendar years 2019 and 2020, $12; and

''(bb) for each subsequent calendar year, $12 multiplied by any percent increase in the Consumer Price Index for all urban consumers (all items; U.S. city average) since calendar year 2020.''; and

(2) by adding at the end the following:

''(C) DETERMINATION OF APPLICABILITY.—

''(i) IN GENERAL.—The Secretary shall, notwithstanding subparagraph (A)(iii) or any determination of substantial equivalence, if any of the conditions specified in clause (ii) are met—

''(I) withdraw any exemption applicable to a tobacco product or products described in such subparagraph;

''(II) require that applications for review under this section be submitted with respect to such product or products; and

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

''(ii) CONDITIONS.—The conditions specified in this clause are that—

''(I) the Secretary determines that the use of a tobacco product or products described in subparagraph (A)(iii) has resulted in an emerging public health threat;

''(II) data from a National Youth Tobacco Survey (or successor survey) conducted after the date of the enactment of the Reversing the Youth Tobacco Epidemic Act of 2019 identifies a rise in youth usage of tobacco products described in section 910(a)(2)(A)(iii); or

''(III) the Secretary determines that a tobacco product or products no longer meets the criteria specified in such subparagraph.''.

(b) NATIONAL ACADEMIES STUDY AND REPORT.—

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

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

(B) the youth usage of such tobacco products; and

(C) the market share of such products.

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