116TH CONGRESS
2D SESSION

S. 3223

To apply user fees with respect to tobacco products deemed subject to the requirements of chapter IX of the Federal Food, Drug, and Cosmetic Act.

IN THE SENATE OF THE UNITED STATES

JANUARY 21, 2020

Mrs. SHAHEEN (for herself, Ms. MURKOWSKI, Mr. DURBIN, Mr. ROMNEY, Ms. BALDWIN, and Ms. COLLINS) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

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A BILL

To apply user fees with respect to tobacco products deemed subject to the requirements of chapter IX of the Federal Food, Drug, and Cosmetic Act.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Resources to Prevent Youth Vaping Act''.

SEC. 2. USER FEES.

(a) INCREASE IN TOTAL AMOUNT.—Section 919(b)(1) of the Federal Food, Drug, and Cosmetic Act

(21 U.S.C. 387s(b)(1)) is amended by striking subparagraph (K) and inserting the following subparagraphs:

''(K) For fiscal year 2019, $712,000,000.

''(L) For fiscal year 2020, $812,000,000.

''(M) For each subsequent fiscal year, the amount that was applicable for the previous fiscal year, adjusted by the total percentage change that occurred in the Consumer Price Index for all urban consumers (all items; United States city average) for the 12-month period ending June 30 preceding the fiscal year.''.

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

(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 re-

spect to each such class shall be an amount that is equal to the applicable percentage of each such class for the fiscal year multiplied by the amount specified in paragraph (1) for the fiscal year.

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

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

amount specified in paragraph (1) for the fiscal year', the applicable percentage shall be multiplied by—

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

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

"(II) with respect to each class of tobacco products to which this chapter applies but which is not listed in subparagraph (B)(i), an amount determined pursuant to a formula under subparagraph (C).".

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

"(C) ALLOCATION FOR OTHER TOBACCO PRODUCTS.—

"(i) IN GENERAL.—Beginning with fiscal year 2022, the total user fees as-

sessed 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".

(c) ALLOCATION OF ASSESSMENT WITHIN EACH CLASS OF TOBACCO PRODUCT.—Section 919(b)(4) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 387s(b)(4)) is amended by striking "shall be the percentage determined for purposes of allocations under subsections (e) through (h) of section 625 of Public Law 108–357" and inserting "shall be the percentage determined by the Secretary".

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

(1) by striking paragraph (5);

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

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

''(6) MEMORANDUM OF UNDERSTANDING.—The Secretary shall request the appropriate Federal agency to enter into a memorandum of understanding that provides for the regular and timely transfer from the head of such agency to the Secretary of all necessary information regarding all tobacco product manufacturers and importers required to pay user fees. The Secretary shall maintain all disclosure restrictions established by the head of such agency regarding the information provided under the memorandum of understanding.''.

(e) APPLICABILITY.—The amendments made by subsections (b), (c), and (d) apply beginning with fiscal year 2022. Subject to the amendment made by subsection (a), section 919 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 387s), as in effect on the day before the date

of enactment of this Act, shall apply with respect to fiscal years preceding fiscal year 2022.

SEC. 3. ANNUAL REPORT.

(a) IN GENERAL.—For fiscal year 2020 and each subsequent fiscal year for which fees are collected under section 919 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 387s), the Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs, shall, not later than 180 days after the end of the respective fiscal year for which the report is being prepared, submit to the Committee on Health, Education, Labor, and Pensions and the Committee on Appropriations of the Senate, and the Committee on Energy and Commerce and Committee on Appropriations of the House of Representatives, an annual report with respect to such fees that contains the information required under subsection (b).

(b) REQUIRED INFORMATION.—Each report submitted under subsection (a) shall contain the following information with respect to the fiscal year for which the report is being submitted:

(1) A breakdown of the amount expended by the Food and Drug Administration on each of the following activities:

(A) Compliance and enforcement.

(B) Public education campaigns.

(C) Scientific research and research infrastructure.

(D) Communications.

(E) Leadership, management, oversight, and administrative functions.

(F) Related overhead activities.

(G) Other activities.

(2) Details on the amount expended, and the purpose of such expenditures, on each of the five largest expenditure amounts within each of the categories described in paragraph (1).

(3) A breakdown of the amount expended on activities related to deemed tobacco products versus how much was expended on activities related to combustible tobacco products outlined in the pre-existing categories of tobacco products under section 919 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 387s).

(4) An explanation for how the Food and Drug Administration ensures that the amount of user fees allocated to public education campaigns on youth e-cigarette use and prevention is sufficient to meet the need for education of teens and minors on the dan-

gers of e-cigarettes and other Electronic Nicotine Delivery Systems (ENDS).

(5) A list of the status of submitted, pending, and approved tobacco product applications for each regulatory pathway and class of tobacco product as defined by the Family Smoking Prevention and Tobacco Control Act (Public Law 111–31), including subsequent regulations, for the 3-fiscal year period preceding the fiscal year for which the report is being prepared.

(6) When applicable, a breakdown of the amount or user fees collected under the amendments made by this Act from manufacturers of deemed tobacco products and the amount collected from manufacturers of each of the original pre-existing categories of tobacco products under section 919 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 387s).

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