

117TH CONGRESS
1ST SESSION

S. 2445

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

JULY 22, 2021

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

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.

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 “Resources To Prevent
5 Youth Vaping Act”.

6 **SEC. 2. USER FEES.**

7 (a) INCREASE IN TOTAL AMOUNT.—Section
8 919(b)(1) of the Federal Food, Drug, and Cosmetic Act

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

3 “(K) For each of fiscal years 2019 through
 4 2021, \$712,000,000.

5 “(L) For fiscal year 2022, \$812,000,000.

6 “(M) For fiscal year 2023 and each subse-
 7 quent fiscal year, the amount that was applica-
 8 ble for the previous fiscal year, adjusted by the
 9 total percentage change that occurred in the
 10 Consumer Price Index for all urban consumers
 11 (all items; United States city average) for the
 12 12-month period ending June 30 preceding the
 13 fiscal year.”.

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

16 (1) IN GENERAL.—Subparagraph (A) of section
 17 919(b)(2) of the Federal Food, Drug, and Cosmetic
 18 Act (21 U.S.C. 387s(b)(2)) is amended to read as
 19 follows:

20 “(A) IN GENERAL.—

21 “(i) FISCAL YEARS 2022 AND 2023.—

22 For fiscal years 2022 and 2023, user fees
 23 shall be assessed and collected under sub-
 24 section (a) only with respect to the classes
 25 of tobacco products listed in subparagraph

1 (B)(i), and the total such user fees with re-
2 spect to each such class shall be an
3 amount that is equal to the applicable per-
4 centage of each such class for the fiscal
5 year multiplied by the amount specified in
6 paragraph (1) for the fiscal year.

7 “(ii) SUBSEQUENT FISCAL YEARS.—
8 For fiscal year 2024 and each subsequent
9 fiscal year, user fees shall be assessed and
10 collected under subsection (a) with respect
11 to each class of tobacco products to which
12 this chapter applies (including tobacco
13 products that the Secretary by regulation
14 deems to be subject to this chapter), and
15 the total user fees with respect to each
16 such class shall be—

17 “(I) with respect to each class of
18 tobacco products listed in subpara-
19 graph (B)(i), an amount that is cal-
20 culated in the same way as the
21 amounts calculated for fiscal years
22 2022 and 2023 under clause (i), ex-
23 cept that for purposes of fiscal years
24 2024 and subsequent fiscal years, in-
25 stead 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.—

1 “(i) IN GENERAL.—Beginning with
2 fiscal year 2024, the total user fees as-
3 sessed and collected under subsection (a)
4 each fiscal year with respect to each class
5 of tobacco products not listed in subpara-
6 graph (B)(i) shall be an amount that is de-
7 termined pursuant to a formula developed
8 by the Secretary by regulation using infor-
9 mation required to be submitted under
10 subparagraph (D).

11 “(ii) ALLOCATION FOR OTHER TO-
12 BACCO PRODUCTS.—For each class of to-
13 bacco products not listed in subparagraph
14 (B)(i), the percentage of fees under the
15 formula under clause (i) for the respective
16 fiscal year shall be equal to the percentage
17 of the gross domestic sales in the previous
18 calendar year that is attributable to such
19 class of tobacco products in such calendar
20 year, as determined by the Secretary.

21 “(iii) ALLOCATION OF ASSESSMENT
22 WITHIN EACH CLASS OF OTHER TOBACCO
23 PRODUCTS.—The percentage of the total
24 user fee to be paid by each manufacturer
25 or importer of tobacco products in a class

1 not listed in subparagraph (B)(i) shall be
2 determined by the Secretary, based on the
3 percentage of the gross domestic sales of
4 all such classes of tobacco products by all
5 manufacturers and importers in the pre-
6 vious calendar year that is attributable to
7 such manufacturer or importer.

8 “(iv) EFFECT OF FAILURE TO FINAL-
9 IZE FORMULA ON TIME.—If the Secretary
10 for any reason fails to finalize by fiscal
11 year 2024 the formula required by this
12 subparagraph for the assessment and col-
13 lection of user fees for classes of tobacco
14 products not listed in subparagraph
15 (B)(i)—

16 “(I) the Secretary shall continue
17 to assess and collect fees under sub-
18 section (a) with respect to each class
19 of tobacco products listed in subpara-
20 graph (B)(i); and

21 “(II) until the first fiscal year
22 commencing after the finalization of
23 such formula, the exception described
24 in subparagraph (A)(ii)(I) shall not
25 apply.

1 “(v) REVISIONS BY REGULATION.—

2 Any revisions to the formula promulgated
3 pursuant to this subparagraph shall be by
4 regulation.

5 “(vi) DEFINITION.—In this subpara-
6 graph, the term ‘gross domestic sales’
7 means the total value in dollars of the sale
8 or distribution by manufacturers and im-
9 porters of tobacco products in the United
10 States in classes not listed in subpara-
11 graph (B)(i), as determined based on the
12 aggregation of sales data from every man-
13 ufacturer and importer of tobacco products
14 that submits sales data to the Secretary.

15 “(D) INFORMATION REQUIRED TO BE SUB-
16 MITTED.—Each manufacturer or importer of
17 any tobacco product shall submit to the Sec-
18 retary the information required under this sub-
19 paragraph by March 1, 2023, for calendar year
20 2022, by April 1, 2023, for the period of Janu-
21 ary 1, 2023, through March 30, 2023, and
22 monthly thereafter. Such information shall in-
23 clude—

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

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

4 “(iii) the full listing of the finished to-
 5 bacco products in a class not listed in sub-
 6 paragraph (B)(i) sold or distributed by the
 7 manufacturer or importer in the United
 8 States; and

9 “(iv) the gross domestic sales data for
 10 each class of finished tobacco products sold
 11 or distributed by the manufacturer or im-
 12 porter in the United States.”.

13 (3) PROHIBITED ACT.—Section 301(q)(1)(B) of
 14 the Federal Food, Drug, and Cosmetic Act (21
 15 U.S.C. 331(q)(1)(B)) is amended by inserting
 16 “919(b)(2)(D),” before “or 920”.

17 (c) ALLOCATION OF ASSESSMENT WITHIN EACH
 18 CLASS OF TOBACCO PRODUCT.—Section 919(b)(4) of the
 19 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
 20 387s(b)(4)) is amended by striking “shall be the percent-
 21 age determined for purposes of allocations under sub-
 22 sections (e) through (h) of section 625 of Public Law 108–
 23 357” and inserting “shall be the percentage determined
 24 by the Secretary”.

1 (d) CONFORMING AMENDMENTS.—Section 919(b) of
2 the 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 redesign-
8 nated, to read as follows:

9 “(6) MEMORANDUM OF UNDERSTANDING.—The
10 Secretary shall request the appropriate Federal
11 agency to enter into a memorandum of under-
12 standing that provides for the regular and timely
13 transfer from the head of such agency to the Sec-
14 retary of all necessary information regarding all to-
15 bacco product manufacturers and importers required
16 to pay user fees. The Secretary shall maintain all
17 disclosure restrictions established by the head of
18 such agency regarding the information provided
19 under the memorandum of understanding.”.

20 (e) APPLICABILITY.—The amendments made by sub-
21 sections (b), (c), and (d) apply beginning with fiscal year
22 2024. Subject to the amendment made by subsection (a),
23 section 919 of the Federal Food, Drug, and Cosmetic Act
24 (21 U.S.C. 387s), as in effect on the day before the date

1 of enactment of this Act, shall apply with respect to fiscal
2 years preceding fiscal year 2024.

3 **SEC. 3. ANNUAL REPORT.**

4 (a) IN GENERAL.—For fiscal year 2022 and each
5 subsequent fiscal year for which fees are collected under
6 section 919 of the Federal Food, Drug, and Cosmetic Act
7 (21 U.S.C. 387s), the Secretary of Health and Human
8 Services, acting through the Commissioner of Food and
9 Drugs, shall, not later than 180 days after the end of the
10 respective fiscal year for which the report is being pre-
11 pared, submit to the Committee on Health, Education,
12 Labor, and Pensions and the Committee on Appropria-
13 tions of the Senate, and the Committee on Energy and
14 Commerce and Committee on Appropriations of the House
15 of Representatives, an annual report with respect to such
16 fees that contains the information required under sub-
17 section (b).

18 (b) REQUIRED INFORMATION.—Each report sub-
19 mitted under subsection (a) shall contain the following in-
20 formation with respect to the fiscal year for which the re-
21 port is being submitted:

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

25 (A) Compliance and enforcement.

1 (B) Public education campaigns.

2 (C) Scientific research and research infra-
3 structure.

4 (D) Communications.

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

7 (F) Related overhead activities.

8 (G) Other activities.

9 (2) Details on the amount expended, and the
10 purpose of such expenditures, on each of the five
11 largest expenditure amounts within each of the cat-
12 egories described in paragraph (1).

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

20 (4) An explanation for how the Food and Drug
21 Administration ensures that the amount of user fees
22 allocated to public education campaigns on youth e-
23 cigarette use and prevention is sufficient to meet the
24 need for education of teens and minors on the dan-
25 gers of e-cigarettes and other Electronic Nicotine

1 Delivery Systems (commonly referred to as
2 “ENDS”).

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

11 (6) When applicable, a breakdown of the
12 amount or user fees collected under the amendments
13 made by this Act from manufacturers of deemed to-
14 bacco products and the amount collected from man-
15 ufacturers of each of the original pre-existing cat-
16 egories of tobacco products under section 919 of the
17 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
18 387s).

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