

119TH CONGRESS
2D SESSION

S. _____

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

Mrs. SHAHEEN introduced the following bill; which was read twice and referred to the Committee on _____

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
9 (21 U.S.C. 387s(b)(1)) is amended by striking subpara-
10 graph (K) and inserting the following subparagraphs:

1 “(K) For each of fiscal years 2019 through
2 2026, \$712,000,000.

3 “(L) For fiscal year 2027, \$826,200,000.

4 “(M) For fiscal year 2028 and each subse-
5 quent fiscal year, the amount that was applica-
6 ble for the previous fiscal year, adjusted by the
7 total percentage change that occurred in the
8 Consumer Price Index for all urban consumers
9 (all items; United States city average) for the
10 12-month period ending June 30 preceding the
11 fiscal year.”.

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

14 (1) IN GENERAL.—Subparagraph (A) of section
15 919(b)(2) of the Federal Food, Drug, and Cosmetic
16 Act (21 U.S.C. 387s(b)(2)) is amended to read as
17 follows:

18 “(A) IN GENERAL.—

19 “(i) FISCAL YEARS 2027 AND 2028.—
20 For fiscal years 2027 and 2028, user fees
21 shall be assessed and collected under sub-
22 section (a) only with respect to the classes
23 of tobacco products listed in subparagraph
24 (B)(i), and the total such user fees with re-
25 spect to each such class shall be an

1 amount that is equal to the applicable per-
2 centage of each such class for the fiscal
3 year multiplied by the amount specified in
4 paragraph (1) for the fiscal year.

5 “(ii) SUBSEQUENT FISCAL YEARS.—
6 For fiscal year 2029 and each subsequent
7 fiscal year, user fees shall be assessed and
8 collected under subsection (a) with respect
9 to each class of tobacco products to which
10 this chapter applies (including tobacco
11 products that the Secretary by regulation
12 deems to be subject to this chapter), and
13 the total user fees with respect to each
14 such class shall be—

15 “(I) with respect to each class of
16 tobacco products listed in subpara-
17 graph (B)(i), an amount that is cal-
18 culated in the same way as the
19 amounts calculated for fiscal years
20 2027 and 2028 under clause (i), ex-
21 cept that for purposes of fiscal years
22 2029 and subsequent fiscal years, in-
23 stead of multiplying the applicable
24 percentage of each such class by ‘the
25 amount specified in paragraph (1) for

1 the fiscal year’, the applicable percent-
2 age shall be multiplied by—

3 “(aa) the amount specified
4 in paragraph (1) for the fiscal
5 year, reduced by

6 “(bb) the total user fees as-
7 sessed and collected pursuant to
8 subparagraph (C) for the fiscal
9 year; and

10 “(II) with respect to each class of
11 tobacco products to which this chapter
12 applies but which is not listed in sub-
13 paragraph (B)(i), an amount deter-
14 mined pursuant to a formula under
15 subparagraph (C).”.

16 (2) OTHER TOBACCO PRODUCTS.—Section
17 919(b)(2) of the Federal Food, Drug, and Cosmetic
18 Act (21 U.S.C. 387s(b)(2)), as amended by para-
19 graph (1), is further amended by adding at the end
20 the following new subparagraphs:

21 “(C) ALLOCATION FOR OTHER TOBACCO
22 PRODUCTS.—

23 “(i) IN GENERAL.—Beginning with
24 fiscal year 2029, the total user fees as-
25 sessed and collected under subsection (a)

1 each fiscal year with respect to each class
2 of tobacco products not listed in subpara-
3 graph (B)(i) shall be an amount that is de-
4 termined pursuant to a formula developed
5 by the Secretary by regulation using infor-
6 mation required to be submitted under
7 subparagraph (D).

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

18 “(iii) ALLOCATION OF ASSESSMENT
19 WITHIN EACH CLASS OF OTHER TOBACCO
20 PRODUCTS.—The percentage of the total
21 user fees to be paid by each manufacturer
22 or importer of tobacco products in a class
23 not listed in subparagraph (B)(i) shall be
24 determined by the Secretary, based on the
25 percentage of the gross domestic sales of

1 all such classes of tobacco products by all
2 manufacturers and importers in the pre-
3 vious calendar year that is attributable to
4 such manufacturer or importer.

5 “(iv) EFFECT OF FAILURE TO FINAL-
6 IZE FORMULA ON TIME.—If the Secretary
7 for any reason fails to finalize by fiscal
8 year 2029 the formula required by this
9 subparagraph for the assessment and col-
10 lection of user fees for classes of tobacco
11 products not listed in subparagraph
12 (B)(i)—

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

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

23 “(v) REVISIONS BY REGULATION.—
24 Any revisions to the formula promulgated

1 pursuant to this subparagraph shall be by
2 regulation.

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

13 “(D) INFORMATION REQUIRED TO BE SUB-
14 MITTED.—Each manufacturer or importer of
15 any tobacco product shall submit to the Sec-
16 retary the information required under this sub-
17 paragraph by March 1, 2028, for calendar year
18 2027, by April 1, 2028, for the period of Janu-
19 ary 1, 2028, through March 31, 2028, and
20 monthly thereafter. Such information shall in-
21 clude—

22 “(i) the identification of the manufac-
23 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 redesignig-
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) shall apply beginning with fiscal
22 year 2029. Except for the amendment made by subsection
23 (a), section 919 of the Federal Food, Drug, and Cosmetic
24 Act (21 U.S.C. 387s), as in effect on the day before the

1 date of enactment of this Act, shall apply with respect to
2 fiscal years preceding fiscal year 2029.

3 **SEC. 3. ANNUAL REPORTING ON TOBACCO REGULATION**
4 **ACTIVITIES.**

5 (a) IN GENERAL.—Section 112(b) of division P of the
6 Consolidated Appropriations Act, 2022 (21 U.S.C.
7 387v(b)) is amended by adding at the end the following:

8 “(12) A breakdown of the amount expended on
9 activities related to deemed tobacco products versus
10 the amount expended on activities related to com-
11 bustible tobacco products listed in section
12 919(b)(2)(B)(i) of the Federal Food, Drug, and Cos-
13 metic Act (21 U.S.C. 387s(b)(2)(B)(i)).

14 “(13) An explanation for how the Food and
15 Drug Administration ensures that the amount of
16 user fees allocated to public education campaigns on
17 youth e-cigarette use and prevention is sufficient to
18 meet the need for education of teens and minors on
19 the dangers of e-cigarettes and other Electronic Nic-
20 otine Delivery Systems (commonly referred to as
21 ‘ENDS’).

22 “(14) When applicable, a breakdown of the
23 amount or user fees collected under the amendments
24 made by this Act from manufacturers of deemed to-
25 bacco products and the amount collected from man-

1 ufacturers of each of the original pre-existing cat-
2 egories of tobacco products under section
3 919(b)(2)(B)(i) of the Federal Food, Drug, and Cos-
4 metic Act (21 U.S.C. 387s(b)(2)(B)(i)).”.

5 (b) APPLICATION.—The information described in
6 paragraphs (12) and (13) of subsection (b) of section 112
7 of division P of the Consolidated Appropriations Act, 2022
8 (21 U.S.C. 387v(b)), as added by subsection (a), shall be
9 required to be included in reports under such section 112
10 for fiscal year 2027 and each subsequent fiscal year, and
11 the information described in paragraph (14) of such sec-
12 tion 112, as added by subsection (a), shall be required to
13 be included in reports under such section 112 for fiscal
14 year 2029 and each subsequent fiscal year.