

116TH 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 (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 _____

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 fiscal year 2019, \$712,000,000.

4 “(L) For fiscal year 2020, \$812,000,000.

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

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

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

19 “(A) IN GENERAL.—

20 “(i) FISCAL YEARS 2020 AND 2021.—

21 For fiscal years 2020 and 2021, user fees
22 shall be assessed and collected under sub-
23 section (a) only with respect to the classes
24 of tobacco products listed in subparagraph
25 (B)(i), and the total such user fees with re-

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

6 “(ii) SUBSEQUENT FISCAL YEARS.—
7 For fiscal year 2022 and each subsequent
8 fiscal year, user fees shall be assessed and
9 collected under subsection (a) with respect
10 to each class of tobacco products to which
11 this chapter applies (including tobacco
12 products that the Secretary by regulation
13 deems to be subject to this chapter), and
14 the total user fees with respect to each
15 such class shall be—

16 “(I) with respect to each class of
17 tobacco products listed in subpara-
18 graph (B)(i), an amount that is cal-
19 culated in the same way as the
20 amounts calculated for fiscal years
21 2020 and 2021 under clause (i), ex-
22 cept that for purposes of fiscal years
23 2022 and subsequent fiscal years, in-
24 stead of multiplying the applicable
25 percentage of each such class by ‘the

1 amount specified in paragraph (1) for
2 the fiscal year', the applicable percent-
3 age shall be multiplied by—

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

7 “(bb) the total user fees as-
8 sessed and collected pursuant to
9 subclause (II) for the fiscal year;
10 and

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

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

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

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

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

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

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

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

6 “(iv) EFFECT OF FAILURE TO FINAL-
7 IZE FORMULA ON TIME.—If the Secretary
8 for any reason fails to finalize by fiscal
9 year 2022 the formula required by this
10 subparagraph for the assessment and col-
11 lection of user fees for classes of tobacco
12 products not listed in subparagraph
13 (B)(i)—

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

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

24 “(v) REVISIONS BY REGULATION.—
25 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, 2021, for calendar year
18 2020, by April 1, 2021, for the period of Janu-
19 ary 1, 2021, through March 30, 2021, 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 redesign-
8 dated, 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 2022. 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 2022.

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

4 (a) **IN GENERAL.**—For fiscal year 2020 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-

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