

116TH CONGRESS  
2D SESSION

# H. R. 5721

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.

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## IN THE HOUSE OF REPRESENTATIVES

JANUARY 30, 2020

Mrs. BUSTOS introduced the following bill; which was referred to the Committee on Energy and Commerce

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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.

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

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

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

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

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

17 “(A) IN GENERAL.—

18 “(i) FISCAL YEARS 2020 AND 2021.—  
19 For fiscal years 2020 and 2021, user fees  
20 shall be assessed and collected under sub-  
21 section (a) only with respect to the classes  
22 of tobacco products listed in subparagraph  
23 (B)(i), and the total such user fees with re-  
24 spect to each such class shall be an  
25 amount that is equal to the applicable per-

1 centage of each such class for the fiscal  
2 year multiplied by the amount specified in  
3 paragraph (1) for the fiscal year.

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

14 “(I) with respect to each class of  
15 tobacco products listed in subpara-  
16 graph (B)(i), an amount that is cal-  
17 culated in the same way as the  
18 amounts calculated for fiscal years  
19 2020 and 2021 under clause (i), ex-  
20 cept that for purposes of fiscal years  
21 2022 and subsequent fiscal years, in-  
22 stead of multiplying the applicable  
23 percentage of each such class by ‘the  
24 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 subclause (II) for the fiscal year;  
9 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 2022, 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 fee 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 2022 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, 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 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 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).

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