

118TH CONGRESS
2D SESSION

H. R. 9425

To amend the Federal Food, Drug, and Cosmetic Act to authorize tobacco user fee assessments for all regulated tobacco products, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

AUGUST 30, 2024

Ms. McCLELLAN introduced the following bill; which was referred to the Committee on Energy and Commerce

A BILL

To amend the Federal Food, Drug, and Cosmetic Act to authorize tobacco user fee assessments for all regulated tobacco products, and for other purposes.

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 “Tobacco User Fee
5 Modernization Act of 2024”.

6 **SEC. 2. TOBACCO PRODUCT 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:

3 “(K) For each of fiscal years 2019 through
 4 2024, \$712,000,000.

5 “(L) For fiscal year 2025, \$826,200,000.

6 “(M) For fiscal year 2026 and each subse-
 7 quent fiscal year, the amount that was applica-
 8 ble for the previous fiscal year, increased 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 TOBACCO
 15 PRODUCTS.—Subparagraph (A) of section 919(b)(2) of
 16 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
 17 387s(b)(2)) is amended to read as follows:

18 “(A) IN GENERAL.—

19 “(i) FISCAL YEARS 2025 THROUGH
 20 2027.—For fiscal years 2025 through
 21 2027, user fees shall be assessed and col-
 22 lected under subsection (a) only with re-
 23 spect to the classes of tobacco products
 24 listed in subparagraph (B)(i), and the total
 25 such user fees with respect to each such

1 class shall be an amount that is equal to
 2 the applicable percentage of each such
 3 class for the fiscal year, as determined in
 4 accordance with subparagraph (B)(ii), mul-
 5 tiplied by the amount specified in para-
 6 graph (1) for the fiscal year.

7 “(ii) SUBSEQUENT FISCAL YEARS.—
 8 Except as specified in subparagraph (C),
 9 for fiscal year 2028 and each subsequent
 10 fiscal year, user fees shall be assessed and
 11 collected under subsection (a) with respect
 12 to each class of tobacco products listed in
 13 subparagraph (B)(i) and other tobacco
 14 products as follows:

15 “(I) For the classes of tobacco
 16 products listed in subparagraph
 17 (B)(i):

18 “(aa) For each fiscal year,
 19 the total user fees assessed and
 20 collected for all the classes of to-
 21 bacco products listed in subpara-
 22 graph (B)(i) together shall be an
 23 amount that is equal to the prod-
 24 uct obtained by multiplying—

1 “(AA) the total of the
2 sum of the gross domestic
3 sales for the classes of to-
4 bacco products listed in sub-
5 paragraph (B)(i) during the
6 previous full calendar year,
7 divided by the sum of the
8 gross domestic sales for the
9 classes of tobacco products
10 listed in subparagraph
11 (B)(i) and other tobacco
12 products during such cal-
13 endar year; by

14 “(BB) the amount
15 specified in paragraph (1)
16 for such fiscal year.

17 “(bb) For each fiscal year,
18 the total user fees assessed and
19 collected for each individual class
20 of tobacco products listed in sub-
21 paragraph (B)(i) shall be an
22 amount that is equal to the prod-
23 uct obtained by multiplying—

24 “(AA) the applicable
25 percentage for each class as

1 determined under subpara-
2 graph (B)(ii); by

3 “(BB) the amount de-
4 termined under subitem
5 (aa).

6 “(II) For other tobacco products,
7 for each fiscal year, the total user fees
8 assessed and collected for all such
9 other tobacco products shall be an
10 amount that is equal to the product
11 obtained by multiplying—

12 “(aa) the total of the gross
13 domestic sales for other tobacco
14 products during the previous full
15 calendar year, divided by the sum
16 of the gross domestic sales for
17 the classes of tobacco products
18 listed in subparagraph (B)(i) and
19 other tobacco products during
20 such calendar year; by

21 “(bb) the amount specified
22 in paragraph (1) for such fiscal
23 year.”.

24 (c) OTHER TOBACCO PRODUCTS.—

1 (1) AMENDMENT.—Section 919(b)(2) of the
2 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
3 387s(b)(2)) is amended by adding at the end the fol-
4 lowing:

5 “(C) EFFECT OF FAILURE TO FINALIZE
6 REGULATIONS ON TIME.—The Secretary shall
7 finalize updates to the regulations under part
8 1150 of title 21, Code of Federal Regulations,
9 to provide for the assessment and collection of
10 user fees for other tobacco products beginning
11 not later than fiscal year 2028. The Secretary
12 shall continue to assess and collect fees under
13 subsection (a) with respect to each class of to-
14 bacco products listed in subparagraph (B)(i)
15 until the first fiscal year commencing after the
16 effective date of the final regulation to imple-
17 ment provisions for assessment and collection of
18 user fees for other tobacco products.

19 “(D) INFORMATION TO BE SUBMITTED.—

20 “(i) IN GENERAL.—In addition to any
21 other reporting requirements under this
22 Act and any implementing regulation, each
23 manufacturer or importer of any tobacco
24 product shall submit to the Secretary the

1 information required under this subpara-
2 graph—

3 “(I) not later than—

4 “(aa) March 1, 2027, for
5 calendar year 2026; and

6 “(bb) April 20, 2027, for
7 the period of January 1, 2027,
8 through March 30, 2027; and

9 “(II) quarterly thereafter, or in
10 accordance with such other reporting
11 requirements as the Secretary may es-
12 tablish by regulation.

13 “(ii) REQUIREMENTS.—The informa-
14 tion required to be submitted under this
15 subparagraph shall consist of—

16 “(I) the identification informa-
17 tion of the manufacturer or importer,
18 to include—

19 “(aa) the Employer Identi-
20 fication Number (EIN);

21 “(bb) company name;

22 “(cc) the phone number (in-
23 cluding area code);

24 “(dd) the email address; and

1 “(ee) the mailing address
2 where communications and as-
3 sessments from the Food and
4 Drug Administration can be re-
5 ceived;

6 “(II) the class or classes of to-
7 bacco products, to include the classes
8 listed in subparagraph (B)(i) and
9 other tobacco products, for which the
10 manufacturer or importer has domes-
11 tic sales; and

12 “(III) the gross domestic sales
13 data, where the manufacturer or im-
14 porter has domestic sales, for each
15 class of tobacco products listed in sub-
16 paragraph (B)(i) and other tobacco
17 products.”.

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

22 (d) ALLOCATION OF ASSESSMENTS.—Paragraph (4)
23 of section 919(b) of the Federal Food, Drug, and Cos-
24 metic Act (21 U.S.C. 387s(b)) is amended to read as fol-
25 lows:

1 “(4) ALLOCATION OF ASSESSMENTS.—The per-
 2 centage share of each manufacturer or importer of
 3 a particular class of tobacco products listed in para-
 4 graph (2)(B)(i) and other tobacco products of the
 5 total user fees to be paid by all manufacturers or
 6 importers of that class of tobacco products listed in
 7 paragraph (2)(B)(i) and other tobacco products shall
 8 be—

9 “(A) for tobacco product classes listed in
 10 paragraph (2)(B)(i), the percentage determined
 11 for purposes of allocations under subsections (e)
 12 through (h) of section 625 of Public Law 108–
 13 357 (7 U.S.C. 518d); and

14 “(B) for other tobacco products, the per-
 15 centage determined by dividing—

16 “(i) the total gross domestic sales of
 17 other tobacco products for a manufacturer
 18 or importer for the prior fiscal quarter; by

19 “(ii) the total gross domestic sales of
 20 other tobacco products for all manufactur-
 21 ers and importers for that same quarter.”.

22 (e) REALLOCATIONS.—Clause (iv) of section
 23 919(b)(2)(B) of the Federal Food, Drug, and Cosmetic
 24 Act (21 U.S.C. 387s(b)(2)(B)) is amended to read as fol-
 25 lows:

1 “(iv) REALLOCATIONS.—In the case
 2 of a class or partial class of tobacco prod-
 3 ucts that is not listed in section 901(b) or
 4 deemed by the Secretary in a regulation
 5 under section 901(b) to be subject to this
 6 chapter, the amount of user fees that
 7 would otherwise be assessed to such class
 8 or partial class of tobacco products shall be
 9 reallocated to the classes or partial classes
 10 of tobacco products that are subject to this
 11 chapter in the same manner and based on
 12 the same relative percentages otherwise de-
 13 termined under clause (ii), adjusted as nec-
 14 essary to reflect partial classes if any.”.

15 (f) LIABILITY.—Paragraph (5) of section 919(b) of
 16 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
 17 387s(b)) is amended to read as follows:

18 “(5) ASSESSMENT LIABILITY.—The quarterly
 19 assessment amount owed by a manufacturer or im-
 20 porter of tobacco products listed in paragraph
 21 (2)(B)(i) or other tobacco products shall be—

22 “(A) based on removals (as defined in sec-
 23 tion 5702(j) of the Internal Revenue Code of
 24 1986) or gross domestic sales, as relevant, dur-
 25 ing the prior fiscal period; and

1 “(B) remitted to the Food and Drug Ad-
2 ministration regardless of whether the manufac-
3 turer or importer meets the definition of manu-
4 facturer or importer in the fiscal quarter in
5 which—

6 “(i) the assessment is calculated; or

7 “(ii) the manufacturer or importer re-
8 ceives notification of the amount of assess-
9 ment owed to the Food and Drug Adminis-
10 tration.”.

11 (g) CONFORMING AMENDMENTS.—Paragraph (7) of
12 section 919(b) of the Federal Food, Drug, and Cosmetic
13 Act (21 U.S.C. 387s(b)) is amended to read as follows:

14 “(7) MEMORANDUM OF UNDERSTANDING.—The
15 Secretary may request any appropriate Federal
16 agency to enter into a memorandum of under-
17 standing that provides for the regular and timely
18 transfer from the head of such agency to the Sec-
19 retary of information regarding any tobacco product
20 manufacturer or importer required to pay user fees.
21 The Secretary shall maintain all disclosure restric-
22 tions established by the head of such agency regard-
23 ing the information provided under the memo-
24 randum of understanding.”.

1 (h) DEFINITIONS.—Section 919(b) of the Federal
2 Food, Drug, and Cosmetic Act (21 U.S.C. 387s(b)) is
3 amended by adding at the end the following:

4 “(8) DEFINITIONS.—For purposes of this sub-
5 section:

6 “(A) The term ‘gross domestic sales’
7 means the total amount in dollars, not to in-
8 clude taxes, duties, and fees, of the sale by
9 manufacturers and importers of finished to-
10 bacco products in the United States.

11 “(B) The term ‘other tobacco product’
12 means a tobacco product that is made or de-
13 rived from tobacco, or contains nicotine from
14 any source, that does not fit within a product
15 class listed in paragraph (2)(B)(i).”.

16 (i) INSPECTION AUTHORITY.—The fifth sentence of
17 section 704(a)(1) of the Federal Food, Drug, and Cos-
18 metic Act (21 U.S.C. 374(a)(1)) is amended by striking
19 “sales data other than shipment data, pricing data” and
20 inserting “sales data (other than shipment data and, for
21 tobacco products, sales data relating to tobacco product
22 user fees under section 919), pricing data (other than
23 pricing data relating to tobacco product user fees under
24 section 919)”.

25 (j) APPLICABILITY.—

1 (1) IN GENERAL.—The amendments made by
2 this section shall apply—

3 (A) in the case of such amendments made
4 by subsections (a), (e), and (i), beginning on
5 the date of enactment of this Act; and

6 (B) in the case of other amendments made
7 by this section, beginning on October 1, 2027.

8 (2) SPECIAL RULE.—If the date of enactment
9 of this Act occurs after fiscal year 2024, then the
10 Secretary of Health and Human Services shall as-
11 sess and collect the increase in total amount by tak-
12 ing the amount specified in subparagraph (L) or
13 (M) of section 919(b)(1) of the Federal Food, Drug,
14 and Cosmetic Act (21 U.S.C. 387c(b)(1)), as appro-
15 priate, and assessing such amount equally across
16 each fiscal quarter for the relevant fiscal year.

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