

116TH CONGRESS
1ST SESSION

S. _____

To impose user fees on manufacturers and importers of electronic nicotine delivery systems.

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 impose user fees on manufacturers and importers of electronic nicotine delivery systems.

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 “E-Cigarette Youth
5 Protection Act”.

6 **SEC. 2. USER FEES RELATING TO ELECTRONIC NICOTINE**
7 **DELIVERY SYSTEMS.**

8 (a) IN GENERAL.—Chapter IX of the Federal Food,
9 Drug, and Cosmetic Act (21 U.S.C. 387 et seq.) is amend-
10 ed by inserting after section 919 the following:

1 **“SEC. 919A. USER FEES RELATING TO ELECTRONIC NICO-**
2 **TINE DELIVERY SYSTEMS.**

3 “(a) ESTABLISHMENT OF QUARTERLY FEE.—Begin-
4 ning on the date of enactment of the E-Cigarette Youth
5 Protection Act, the Secretary shall in accordance with this
6 section assess user fees on, and collect such fees from,
7 each manufacturer and importer of electronic nicotine de-
8 livery systems. The fees shall be assessed and collected
9 with respect to each quarter of each fiscal year, and the
10 total amount assessed and collected for a fiscal year shall
11 be the amount specified in subsection (b)(1) for such year,
12 subject to subsection (c).

13 “(b) ASSESSMENT OF USER FEE.—

14 “(1) AMOUNT OF ASSESSMENT.—The total
15 amount of user fees authorized to be assessed and
16 collected under subsection (a) for a fiscal year is the
17 following, as applicable to the fiscal year involved:

18 “(A) For fiscal year 2020, the greater of—

19 “(i) \$150,000,000; or

20 “(ii) 2 percent of the total value of
21 manufacturer sales of electronic nicotine
22 delivery systems in the United States in
23 fiscal year 2019.

24 “(B) For fiscal year 2021 and each fiscal
25 year thereafter, the greater of—

1 “(i) the amount described in subpara-
2 graph (A), increased by the percentage in-
3 crease in the Consumer Price Index be-
4 tween 2020 and the applicable year; or

5 “(ii) 2 percent of the total value of
6 manufacturer sales of electronic nicotine
7 delivery systems in the United States in
8 the previous fiscal year.

9 “(2) DETERMINATION OF USER FEE BY COM-
10 PANY.—

11 “(A) IN GENERAL.—The total user fee to
12 be paid by each manufacturer or importer of
13 electronic nicotine delivery systems shall be de-
14 termined for each quarter by multiplying—

15 “(i) such manufacturer’s or importer’s
16 percentage share of the total electronic nic-
17 otine delivery system market in the United
18 States; by

19 “(ii) the portion of the user fee
20 amount for the current quarter to be as-
21 sessed on all manufacturers and importers
22 under paragraph (1).

23 “(B) NO FEE IN EXCESS OF PERCENTAGE
24 SHARE.—No manufacturer or importer of elec-
25 tronic nicotine delivery systems shall be re-

1 required to pay a user fee in excess of the per-
2 centage share of the total electronic nicotine de-
3 livery system market of the manufacturer or
4 importer.

5 “(3) TIMING OF ASSESSMENT.—The Secretary
6 shall notify each manufacturer and importer of elec-
7 tronic nicotine delivery systems subject to this sec-
8 tion of the amount of the quarterly assessment im-
9 posed on such manufacturer or importer under this
10 subsection for each quarter of each fiscal year. Such
11 notifications shall occur not later than 30 days prior
12 to the end of the quarter for which such assessment
13 is made, and payments of all assessments shall be
14 made by the last day of the quarter involved.

15 “(4) CALCULATION OF MARKET SHARE.—Be-
16 ginning not later than fiscal year 2020, and for each
17 subsequent fiscal year, the Secretary shall ensure
18 that the Food and Drug Administration is able to
19 determine—

20 “(A) the annual amount of total sales in
21 the electronic nicotine delivery system market of
22 the United States; and

23 “(B) the applicable percentage shares
24 under paragraph (2)(A).

25 “(c) CREDITING AND AVAILABILITY OF FEES.—

1 “(1) IN GENERAL.—Fees authorized under sub-
2 section (a) shall be collected and available for obliga-
3 tion only to the extent and in the amount provided
4 in advance in appropriations Acts. Such fees are au-
5 thorized to remain available until expended. Such
6 sums as may be necessary may be transferred from
7 the Food and Drug Administration salaries and ex-
8 penses appropriation account without fiscal year lim-
9 itation to such appropriation account for salaries
10 and expenses with such fiscal year limitation.

11 “(2) AUTHORIZATION OF APPROPRIATIONS.—
12 For fiscal year 2021 and each subsequent fiscal
13 year, there is authorized to be appropriated for fees
14 under this section an amount equal to the amount
15 specified in subsection (b)(1) for the fiscal year.

16 “(d) COLLECTION OF UNPAID FEES.—In any case
17 where the Secretary does not receive payment of a fee as-
18 sessed under subsection (a) within 30 days after it is due,
19 such fee shall be treated as a claim of the United States
20 Government subject to subchapter II of chapter 37 of title
21 31, United States Code.

22 “(e) APPLICABILITY TO FISCAL YEAR 2020.—If the
23 date of enactment of the E-Cigarette Youth Protection Act
24 occurs during fiscal year 2020, subject to subsection (c),
25 for the quarter following the quarter in which such date

1 of enactment occurs, the full quarterly fee amounts shall
2 be assessed and collected.”.

3 (b) ENFORCEMENT.—

4 (1) IN GENERAL.—Section 902(4) of the Fed-
5 eral Food, Drug, and Cosmetic Act (21 U.S.C.
6 387b(4)) is amended by inserting “, or the manufac-
7 turer or importer of electronic nicotine delivery sys-
8 tems fails to pay a user fee assessed to such manu-
9 facturer or importer pursuant to section 919A by
10 the date specified in section 919A or by the 30th
11 day after final agency action on a resolution of any
12 dispute as to the amount of such fee” before the
13 semicolon.

14 (2) EFFECTIVE DATE.—The amendment made
15 by paragraph (1) shall take effect on the later of Oc-
16 tober 1, 2021, or the date of enactment of this Act.

17 (c) DEFINITION.—Section 900 of the Federal Food,
18 Drug, and Cosmetic Act (21 U.S.C. 387) is amended—

19 (1) by redesignating paragraphs (8) through
20 (22) as paragraphs (9) through (23), respectively;
21 and

22 (2) by inserting after paragraph (7) the fol-
23 lowing:

