116TH CONGRESS
1ST SESSION

S. 616

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

IN THE SENATE OF THE UNITED STATES

FEBRUARY 28, 2019

Mrs. SHAHEEN introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

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A BILL

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

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the "E-Cigarette Youth Protection Act".

SEC. 2. USER FEES RELATING TO ELECTRONIC NICOTINE DELIVERY SYSTEMS.

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

"SEC. 919A. USER FEES RELATING TO ELECTRONIC NICOTINE DELIVERY SYSTEMS.

''(a) ESTABLISHMENT OF QUARTERLY FEE.—Beginning on the date of enactment of the E-Cigarette Youth Protection Act, the Secretary shall in accordance with this section assess user fees on, and collect such fees from, each manufacturer and importer of electronic nicotine delivery systems. The fees shall be assessed and collected with respect to each quarter of each fiscal year, and the total amount assessed and collected for a fiscal year shall be the amount specified in subsection (b)(1) for such year, subject to subsection (c).

''(b) ASSESSMENT OF USER FEE.—

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

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

''(i) $150,000,000; or

''(ii) 2 percent of the total value of manufacturer sales of electronic nicotine delivery systems in the United States in fiscal year 2019.

''(B) For fiscal year 2021 and each fiscal year thereafter, the greater of—

"(i) the amount described in subparagraph (A), increased by the percentage increase in the Consumer Price Index between 2020 and the applicable year; or

"(ii) 2 percent of the total value of manufacturer sales of electronic nicotine delivery systems in the United States in the previous fiscal year.

"(2) DETERMINATION OF USER FEE BY COMPANY.—

"(A) IN GENERAL.—The total user fee to be paid by each manufacturer or importer of electronic nicotine delivery systems shall be determined for each quarter by multiplying—

"(i) such manufacturer's or importer's percentage share of the total electronic nicotine delivery system market in the United States; by

"(ii) the portion of the user fee amount for the current quarter to be assessed on all manufacturers and importers under paragraph (1).

"(B) NO FEE IN EXCESS OF PERCENTAGE SHARE.—No manufacturer or importer of electronic nicotine delivery systems shall be re-

quired to pay a user fee in excess of the percentage share of the total electronic nicotine delivery system market of the manufacturer or importer.

''(3) TIMING OF ASSESSMENT.—The Secretary shall notify each manufacturer and importer of electronic nicotine delivery systems subject to this section of the amount of the quarterly assessment imposed on such manufacturer or importer under this subsection for each quarter of each fiscal year. Such notifications shall occur not later than 30 days prior to the end of the quarter for which such assessment is made, and payments of all assessments shall be made by the last day of the quarter involved.

''(4) CALCULATION OF MARKET SHARE.—Beginning not later than fiscal year 2020, and for each subsequent fiscal year, the Secretary shall ensure that the Food and Drug Administration is able to determine—

''(A) the annual amount of total sales in the electronic nicotine delivery system market of the United States; and

''(B) the applicable percentage shares under paragraph (2)(A).

''(c) CREDITING AND AVAILABILITY OF FEES.—

''(1) IN GENERAL.—Fees authorized under subsection (a) shall be collected and available for obligation only to the extent and in the amount provided in advance in appropriations Acts. Such fees are authorized to remain available until expended. Such sums as may be necessary may be transferred from the Food and Drug Administration salaries and expenses appropriation account without fiscal year limitation to such appropriation account for salaries and expenses with such fiscal year limitation.

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

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

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

of enactment occurs, the full quarterly fee amounts shall be assessed and collected.''.

(b) ENFORCEMENT.—

(1) IN GENERAL.—Section 902(4) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 387b(4)) is amended by inserting '', or the manufacturer or importer of electronic nicotine delivery systems fails to pay a user fee assessed to such manufacturer or importer pursuant to section 919A by the date specified in section 919A or by the 30th day after final agency action on a resolution of any dispute as to the amount of such fee'' before the semicolon.

(2) EFFECTIVE DATE.—The amendment made by paragraph (1) shall take effect on the later of October 1, 2021, or the date of enactment of this Act.

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

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

(2) by inserting after paragraph (7) the following:

''(8) ELECTRONIC NICOTINE DELIVERY SYSTEM.—The term 'electronic nicotine delivery system'—

''(A) means any electronic device that delivers nicotine, flavor, or another substance via an aerosolized solution to the user inhaling from the device (including e-cigarettes, e-hookah, e-cigars, vape pens, advanced refillable personal vaporizers, and electronic pipes) and any component, liquid, part, or accessory of such a device, whether or not sold separately; and

''(B) does not include a product that—

''(i) is approved by the Food and Drug Administration for sale as a tobacco cessation product or for another therapeutic purpose; and

''(ii) is marketed and sold solely for a purpose described in clause (i).''.

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