AMENDMENT TO AGRICULTURE AND RURAL DEVELOPMENT APPROPRIATIONS BILL

OFFERED BY _____

At the end of the bill (before the spending reduction account), insert the following:

SEC. ____. (a) None of the funds appropriated or otherwise made available by this Act or any other Act with respect to any fiscal year may be used to implement, administer, or enforce the final rule with the regulation identifier number 0910-AG38 published by the Food and Drug Administration in the Federal Register on May 10, 2016 (81 Fed. Reg. 28974) with respect to traditional large and premium cigars. For the purposes of this section, the term ''traditional large and premium cigar'' means—

(1) any roll of tobacco that is wrapped in 100 percent leaf tobacco, is bunched with 100 percent tobacco filler, contains no filter, tip, or non-tobacco mouthpiece, weighs at least 6 pounds per 1,000 count, and—

(A) has a 100 percent leaf tobacco binder and is hand rolled;

(B) has a 100 percent leaf tobacco binder and is made using human hands to lay the leaf

tobacco wrapper or binder onto only one machine that bunches, wraps, and caps each individual cigar; or

(C) has a homogenized tobacco leaf binder and is made in the United States using human hands to lay each 100 percent leaf tobacco wrapper individually onto a single machine that bunches, wraps, and caps each individual cigar on such single machine and makes no more than 15 cigars per minute; and

(2) is not a cigarette or a little cigar (as such terms are defined in paragraphs (3) and (11), respectively, of section 900 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 387)).

SEC. ____. None of the funds appropriated or otherwise made available by this Act or any other Act with respect to any fiscal year may, for cigars and pipe tobacco, and components and parts thereof, which the Secretary of Health and Human Services by regulation under section 901(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 387a(b)) deems to be subject to chapter IX of such Act, be used to treat any reference in sections 905(j) or 910(a) of such Act (21 U.S.C. 387e(j), 387j(a)) to February 15, 2007, as other than a reference to April 25, 2014, the date of the regulation under which tobacco prod-

ucts were proposed to be deemed subject to the requirements of such chapter pursuant to section 901(b) of such Act (21 U.S.C. 387a(b)).

SEC. ____. (a) Section 905(j)(1)(A)(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 387e(j)(1)(A)(i)) is amended by inserting ''or to a tobacco product subject to an order that the Secretary has issued to such person under subsection (c)(1)(A)(i) of section 910,'' after ''as of February 15, 2007,''.

(b) Section 910(a)(2)(A)(i)(I) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 387j(a)(2)(A)(i)(I)) is amended by inserting '', or to a tobacco product subject to an order that the Secretary has issued to such person under subsection (c)(1)(A)(i)'' after ''as of February 15, 2007''.

SEC. ____. (a) Notwithstanding any other provision of law, not later than 21 months after the date of enactment of this Act, the Secretary of Health and Human Services shall issue a notice of proposed rulemaking to establish a product standard for vapor products pursuant to section 907 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 387g) to include but not be limited to—

(1) characterizing flavors; and

(2) batteries.

(b) Notwithstanding any other provision of law, not later than 36 months after the date of enactment of this Act, the Secretary shall promulgate a final rule pursuant to such notice.

SEC. ____. (a) A vapor product shall be deemed to be misbranded under section 903(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 387c(a)) if the advertising with respect to the vapor product is disseminated by a manufacturer, distributor, or retailer of the product in a newspaper, magazine, periodical, or other publication (including any publication of periodic or limited distribution) other than an adult publication.

(b)(1) A retailer may only sell any vapor product in a direct face-to-face exchange without the assistance of any electronic or mechanical device (such as a vending machine).

(2) This subsection shall not apply with respect to sales of vapor products conducted through—

(A) mail-order; or

(B) a vending machine or self-service display if, with respect to the facility in which such vending machine or display is located, the retailer of such products ensures that no person under 18 years of age is present or permitted to enter.

(3) A violation of this section is deemed to constitute a violation of the Federal Food, Drug, and Cosmetic Act relating to a tobacco product for purposes of section 303(f)(9) of such Act (21 U.S.C. 333(f)(9)).

(c)(1) Not later than 12 months after the date of enactment of this Act, the Secretary of Health and Human Services shall promulgate final regulations to require that the labeling of vapor products contain—

(A) the phrase ''Keep Out of Reach of Children'';

(B) the phrase ''Underage Sale Prohibited''; and

(C) an accurate statement of the nicotine content of the vapor product.

(2) A vapor product whose label is in violation of the regulations required by paragraph (1) is deemed to be misbranded under section 903 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 387c).

(d)(1) Every person who owns or operates an establishment in any State engaged in the retail sale of a vapor product shall register that establishment with the Secretary of Health and Human Services within the later of 60 days after the date of enactment of this Act, or 30 days after first engaging in such retail sale.

(2) The requirements of this subsection do not apply with respect to any establishment subject to an active registration under—

(A) any State law relating to tobacco products; or

(B) section 905 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 387e).

(3) The Secretary shall make available for inspection, to any person so requesting, any registration filed under this section.

(e) In this section:

(1) The term ''adult publication'' means any newspaper, magazine, periodical, or other publication—

(A) whose readers younger than 18 years of age constitute 15 percent or less of the total readership as measured by competent and reliable survey evidence; and

(B) that is read by fewer than 2 million persons younger than 18 years of age as measured by competent and reliable survey evidence.

(2) The terms ''label'' and ''labeling'' have the meanings given to such terms in section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321).

(3) The term ''tobacco product'' has the meaning given to such term in section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321).

(4) The term ''vapor product''—

(A) means any non-combustible product that employs a heating element, power source, electronic circuit, or other electronic, chemical, or mechanical means, regardless of shape or size, to produce vapor from nicotine in a solution or other form;

(B) includes any electronic cigarette, electronic cigar, electronic cigarillo, electronic pipe, or similar product or device, and any vapor cartridge or other container of nicotine in a solution or other form; and

(C) does not include any product regulated as a drug or device by the Food and Drug Administration under chapter V of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351 et. seq.).

SEC. ____. The Pro-Children Act of 1994 (20 U.S.C. 6083) is amended—

(1) by striking ''smoking'' each place it appears in subsections (a), (b), and (c) and inserting ''smoking or use of vapor products''; and

(2) by striking ''smoking'' each place it appears in subsection (e) and inserting ''smoking or vapor product''.

SEC. ____. Section 906(d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 387f(d)) is amended by striking paragraph (4) and inserting the following:

''(4) AGE VERIFICATION FOR REMOTE SALES.—A delivery seller of vapor products—

''(A) shall not sell, deliver, or cause to be delivered any vapor products to a person under the minimum age required for the legal sale or purchase of vapor products, as determined by the applicable law at the place of delivery; and

''(B) shall not accept a delivery sale order from a person without—

''(i) obtaining the full name, birth date, and residential address of that person; and

''(ii) verifying the information provided in clause (i), through the use of a commercially available database or aggregate of databases, consisting primarily of data from government sources, that are regularly used by government and businesses for the purpose of age and identity

verification and authentication, to ensure that the purchaser is at least the minimum age required for the legal sale or purchase of vapor products, as determined by the applicable law at the place of delivery.

''(C) LIMITATION.—No database being used for age and identity verification under subparagraph (B)(ii) shall be in the possession or under the control of the delivery seller, or be subject to any changes or supplementation by the delivery seller.

''(D) DEFINITIONS.—In this paragraph:

''(i) The term 'delivery sale' means a sale of vapor products in which—

''(I) the consumer submits the order for the sale by means of a telephone or other method of voice transmission, the mails, or the Internet or other online service, or the seller is otherwise not in the physical presence of the buyer when the request for purchase or order is made; or

''(II) the vapor products are delivered to the buyer by common carrier, private delivery service, or other

method of remote delivery, or the seller is not in the physical presence of the buyer when the buyer obtains possession of the vapor products.

''(ii) The term 'delivery seller' means a person who makes a delivery sale, or provides an online marketplace to facilitate a delivery sale.

''(iii) The term 'online marketplace' means an online portal or other digital or similar platform that facilitates the sale of products to consumers, through retail sale, auction, or similar transactions.''.

SEC. ____. Not later than 180 days after the date of the enactment of this Act, the Secretary of Health and Human Services shall submit a report to the Committees on Appropriations of both Houses of Congress, the Committee on Health, Education, Labor, and Pensions of the Senate, and the Committee on Energy and Commerce of the House of Representatives, that includes a plan of action with respect to the development and operation of the Youth Vapor Product Education, Prevention, and Enforcement Program.

SEC. ____. (a) The Commissioner of Food and Drugs shall conduct a study on preventing the use of electronic

nicotine delivery systems (referred to in this section as ''ENDS'') by youth. Such study shall include an analysis of—

(1) the potential costs and benefits of using, and requiring the use of, biometric security measures in ENDS—

(A) during premarket development;

(B) at the time of sale; and

(C) during postmarket use;

(2) the effectiveness of such biometric security measures in preventing usage by youth of ENDS;

(3) the potential costs and benefits of requiring such biometric security measures for sales of ENDS made through mail delivery and via the Internet; and

(4) alternative technologies that may assist in preventing usage by youth of ENDS.

(b) The Commissioner of Food and Drugs shall provide a report on the results of the study under subsection (a) to the Committee on Appropriations of both Houses of Congress not later than 180 days after the date of enactment of this Act.

In the first paragraph under the heading ''Food and Drug Administration, Salaries and Expenses'', insert before ''*Provided further,* That funds may be transferred from one specified activity to another with the prior ap-

proval of the Committees on Appropriations of both Houses of Congress'' the following: ''*Provided further,* That $50,000,000 of the amount allocated to the Center for Tobacco Products from tobacco product user fees authorized by section 919 of the Federal Food, Drug, and Cosmetic Act in fiscal years 2019, 2020, 2021, and 2022, shall be used by the Secretary to develop, establish, and operate a Youth Vapor Product Education, Prevention, and Enforcement Program, to include consumer outreach and education targeted to the use of vapor products by minors, optional grants to school systems, nonprofit public health entities, and other qualifying entities for programs and initiatives aimed at youth vapor product and tobacco product prevention, and enforcement of provisions of the Federal Food, Drug and Cosmetic Act relating to youth access to vapor products:''.