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115TH CONGRESS
1ST SESSION

H. R. 2194

To protect the public health by providing the Food and Drug Administration with certain authority to regulate e-liquids and personal electronic vaporizers, to reduce the morbidity and mortality resulting from cigarette smoking through the responsible regulation of e-liquids and personal electronic vaporizers as a tobacco harm reduction strategy, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

APRIL 27, 2017

Mr. HUNTER introduced the following bill; which was referred to the Committee on Energy and Commerce

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A BILL

To protect the public health by providing the Food and Drug Administration with certain authority to regulate e-liquids and personal electronic vaporizers, to reduce the morbidity and mortality resulting from cigarette smoking through the responsible regulation of e-liquids and personal electronic vaporizers as a tobacco harm reduction strategy, and for other purposes.

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

SECTION 1. SHORT TITLE; TABLE OF CONTENTS.

(a) SHORT TITLE.—This Act may be cited as the ''Cigarette Smoking Reduction and Electronic Vapor Alternatives Act of 2017''.

(b) TABLE OF CONTENTS.—The table of contents of this Act is as follows:

SEC. 2. FINDINGS.

The Congress finds the following:

(1) Cigarette smoking is the practice of burning tobacco rolled in a paper and inhaling the smoke. According to the Department of Health and Human Services—

(A) the burning of tobacco produces a chemical mixture of more than 7,000 compounds;

(B) cigarette smoking causes cancer, heart disease, stroke, lung diseases, diabetes, and chronic obstructive pulmonary disease, and harms nearly every organ of the body;

(C) cigarette smoking causes more than 480,000 deaths each year, including nearly 42,000 deaths due to secondhand tobacco smoke;

(D) the economic cost of cigarette smoking is more than $300 billion a year, including nearly $170 billion in direct medical care, and more than $156 billion in lost productivity; and

(E) nearly 7 in 10 adult cigarette smokers want to quit smoking.

(2) Electronic vapor products, also known as ''electronic cigarettes'' or ''e-cigarettes'', are battery-operated devices that use low heat to turn e-liquid, which generally contains nicotine, into a vaporized aerosol which is inhaled—there is no burning of tobacco or generation of smoke for inhalation.

(3) Evidence from numerous studies strongly suggests that electronic vapor products are magnitudes safer than traditional, combustible cigarettes. Studies have found that several million regular vapers in the United States no longer regularly smoke cigarettes.

(4) Studies of cigarette smokers who switched to vapor found significant improvements in lung function, including a study finding asthmatic smokers who switched to vapor had significant improvements in spirometry data, asthma control, airway hyperresponsiveness, and lower blood pressure.

(5) The Royal College of Physicians 2016 report on e-cigarettes titled, ''Nicotine without smoke: Tobacco harm reduction'' issued the following findings:

(A) The available evidence to date indicates that e-cigarettes are being used almost exclusively as safer alternatives to smoked tobacco, by confirmed smokers who are trying to reduce harm to themselves or others from smoking, or to quit smoking completely.

(B) The hazard to health arising from long-term vapor inhalation from the e-cigarettes available today is unlikely to exceed 5 percent of the harm from smoking tobacco.

(C) E-cigarettes are marketed as consumer products and are proving much more popular than Food and Drug Administration-approved nicotine replacement therapies (NRT) as a substitute and competitor for tobacco cigarettes.

(6) ''E-liquid'' is the liquid that is heated into vapor. It contains, principally, propylene glycol, vegetable glycerin, in some cases food flavoring, in some cases nicotine, and in some cases water; propylene glycol and vegetable glycerin are designated as ''gen-

erally recognized as safe'' by the Food and Drug Administration (FDA) as food additives.

(7) Surveys have found that a significant majority of regular users of electronic vapor products had previously tried FDA-approved smoking cessation drugs to quit smoking without success.

(8) An expert independent evidence review published by Public Health England (PHE) concluded that—

(A) the use of vapor products is about 95 percent less harmful than cigarette smoking;

(B) nearly half the population doesn't realize vapor is much less harmful than smoking; and

(C) there is no evidence suggesting electronic vapor products act as a route into smoking for children or nonsmokers.

(9) Electronic vapor product sales in the United States have increased from an estimated $100 million in 2010 to $4 billion in 2016 while cigarette consumption in the United States declined from $307 billion in 2010 to an estimated $265 billion in 2016.

(10) On May 10, 2016, the Food and Drug Administration issued its ''Deeming Regulation'' to

deem e-cigarettes or electronic vapor products to be subject to its authority. The regulation will, as a practical matter, because of its significant compliance costs and poorly articulated standard for protecting public health, ban the sale of all electronic vapor products by August 2018.

(11) The Food and Drug Administration's Deeming Regulation, by effectively banning electronic vapor products, will push vapers who have quit or reduced cigarette smoking by switching to electronic vapor products back to smoking deadly cigarettes.

(12) The 2015 Monitoring the Future survey of the National Institute on Drug Abuse found past-30-day use of an electronic vapor product by 8th, 10th, and 12th graders combined declined from 13.9 percent in 2014 to 9.9 percent in 2016; however, that survey found that fewer than 20 percent of teens who used an electronic vapor product in the past 30 days reported using a product containing nicotine.

(13) Electronic vapor products show tremendous promise in reducing cigarette smoking, and cigarette smoking attributable morbidity, mortality, and health care costs.

(14) According to an April 13, 2017, Centers for Disease Control and Prevention study, more Americans who are trying to quit smoking use vapor products (35.3 percent) than any other smoking cessation tool. This includes using a nicotine patch or gum (25.4 percent), getting help from a doctor or other health professional (15.2 percent), using smoking cessation medications approved by the Food and Drug Administration (12.2 percent), and getting help from a website (7.1 percent) or a telephone quitline (5.4 percent).

(15) Since the Food and Drug Administration was granted authority to regulate tobacco products in 2009, the agency has failed to grant market approval to any modified risk tobacco product.

SEC. 3. PURPOSES OF THE FAMILY SMOKING PREVENTION AND TOBACCO CONTROL ACT.

Section 3 of the Family Smoking Prevention and Tobacco Control Act (21 U.S.C. 387 note) is amended by amending paragraph (9) to read as follows:

''(9) to promote—

''(A) cessation to reduce disease risk and the social costs associated with tobacco-related diseases; and

''(B) harm reduction strategies; and''.

SEC. 4. REGULATION OF ELECTRONIC VAPOR PRODUCTS.

(a) CENTER FOR TOBACCO PRODUCTS AND TOBACCO HARM REDUCTION.—Section 901(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 387a(e)) is amended—

(1) in the subsection heading, by striking ''CENTER FOR TOBACCO PRODUCTS'' and inserting ''CENTER FOR TOBACCO PRODUCTS AND TOBACCO HARM REDUCTION'';

(2) by striking ''Center for Tobacco Products'' and inserting ''Center for Tobacco Products and Tobacco Harm Reduction''; and

(3) by striking ''this chapter'' and inserting ''this chapter and chapter X''.

(b) FDA AUTHORITY OVER ELECTRONIC VAPOR PRODUCTS.—

(1) EXCLUSION FROM DEFINITION OF TOBACCO PRODUCT.—Section 201(rr) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(rr)) is amended—

(A) in paragraph (2), by inserting ''an e-liquid (as defined in section 1001), a personal electronic vaporizer (as defined in section 1001),'' before ''or a combination product''; and

(B) in paragraph (3), by inserting after ''The products described in paragraph (2)'' the

following: ''(other than an e-liquid or personal electronic vaporizer)''.

(2) COMBINATION PRODUCTS.—Section 503(g) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 353(g)) is amended—

(A) in paragraph (1)—

(i) in subparagraph (A), by striking ''or biological product'' and inserting '', biological product, e-liquid, or personal electronic vaporizer''; and

(ii) in subparagraph (D)—

(I) in clause (ii), by striking ''or'' at the end;

(II) in clause (iii), by striking the period at the end and inserting ''; or''; and

(III) by adding at the end the following:

''(iv) an e-liquid or personal electronic vaporizer, the agency center charged with regulating e-liquids and personal electronic vaporizers shall have primary jurisdiction.''; and

(B) in paragraph (9)—

(i) by redesignating subparagraphs (C) and (D) as subparagraphs (D) and (E), respectively; and

(ii) by inserting after subparagraph (B) the following:

''(C) The terms 'e-liquid' and 'personal electronic vaporizer' have the meanings given to such terms in section 1001.''.

(3) REGULATORY AUTHORITY.—The Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) is amended—

(A) by redesignating chapter X as chapter XI;

(B) by redesignating sections 1001 through 1014 as sections 1101 through 1114, respectively;

(C) in section 505(n)(2), by striking ''1004'' and inserting ''1104'';

(D) in sections 523(b)(2)(D) and 704(g)(13), by striking ''1003(g)'' and inserting ''1103(g)'';

(E) in section 1109(a)(5)(A), as redesignated by paragraph (4), by striking ''1008'' and inserting ''1108''; and

(F) by inserting after chapter IX the following:

"CHAPTER X—ELECTRONIC VAPOR PRODUCTS

"SEC. 1001. DEFINITIONS.

''In this chapter:

''(1) The term 'e-liquid' means any liquid solution that—

''(A) may or may not contain nicotine; and

''(B) is intended to be converted into an aerosol, vapor, or vapor-like mist for users to inhale through the mouthpiece of a personal electronic vaporizer.

''(2) The term 'personal electronic vaporizer' means an electronic device that employs a heating element or atomizer that converts an e-liquid into an aerosol, vapor, or vapor-like mist through a non-combustive process.

''(3) The terms 'e-liquid' and 'personal electronic vaporizer' exclude—

''(A) a drug as defined in section 201(g)(1);

''(B) a device as defined in section 201(h); and

''(C) a biological product as defined in section 351 of the Public Health Service Act.

''SEC. 1002. EXCLUSIVE AUTHORITY FOR REGULATING E-LIQUIDS AND PERSONAL ELECTRONIC VAPORIZERS.

''The authorities vested by this chapter constitute the exclusive authorities of the Secretary to regulate e-liquids and personal electronic vaporizers, except to the extent e-liquids and personal electronic vaporizers are within combination products regulated pursuant to section 503(g).

''SEC. 1003. PROHIBITED ACTS; PENALTIES.

''(a) PROHIBITIONS.—

''(1) IN GENERAL.—The following acts and the causing thereof are hereby prohibited:

''(A) The sale of an electronic vapor product or e-liquid to any person younger than 18 years of age.

''(B) The manufacture of an e-liquid or personal electronic vaporizer in noncompliance with the standards under section 1004(b) in violation of an order issued under section 1004(e).

''(C) The offering of e-liquids or personal electronic vaporizers for sale in interstate commerce by an e-liquid or personal electronic va-

porizer manufacturer that does not have a certification in effect as required by section 1004(c).

''(D) The failure by an e-liquid or personal electronic vaporizer manufacturer to provide access for inspection as required by section 1004(d).

''(E) The introduction or delivery for introduction in interstate commerce of an e-liquid or personal electronic vaporizer by any person that is adulterated or misbranded, as described in subsection (b) or (c) respectively.

''(2) RETAILERS.—Notwithstanding subparagraphs (A) and (E) of paragraph (1), a retailer may be found to be in violation of either such subparagraph (with respect to sale or introduction or delivery for introduction in interstate commerce at retail) only if the violation occurs knowingly.

''(b) ADULTERATION.—An e-liquid or personal electronic vaporizer shall be treated as adulterated if—

''(1) it was manufactured in noncompliance with the standards under section 1004(b) in violation of an order issued under section 1004(e); or

''(2) it was manufactured by an e-liquid or personal electronic vaporizer manufacturer that does

not have a certification in effect as required by section 1004(c).

''(c) MISBRANDING.—An e-liquid or personal electronic vaporizer shall be treated as misbranded if its labeling (as such term is defined in section 201 with respect to drugs) is in noncompliance with the standards under section 1004(b) in violation of an order issued under section 1004(e).

''(d) PENALTIES.—Any person who violates a provision of subsection (a) shall be imprisoned not more than 3 years, fined not more than $10,000 (notwithstanding section 3571(e) of title 18, United States Code) for each day on which the violation continues, or both.

''SEC. 1004. STANDARDS FOR THE MANUFACTURING OF E-LIQUIDS AND PERSONAL ELECTRONIC VAPORIZERS; COMPLIANCE.

''(a) REQUIREMENT.—Beginning on the date that is 1 year after the date of enactment of the Cigarette Smoking Reduction and Electronic Vapor Alternatives Act of 2017, any e-liquid or personal electronic vaporizer introduced or delivered for introduction into interstate commerce shall conform to the e-liquid or personal electronic vaporizer (as applicable) manufacturing standards under subsection (b), including the labeling standards therein.

''(b) MANUFACTURING STANDARDS.—

''(1) E-LIQUIDS.—The manufacturing standards for e-liquids under this subsection shall consist of the following:

''(A) INTERIM STANDARDS.—The e-liquid manufacturing standards issued by the American E-Liquid Manufacturing Standards Association (version 2.3.2) on March 8, 2017 (including any revision to such standards made in accordance with paragraph (3)), apply to the introduction or delivery for introduction into interstate commerce of e-liquids during the period beginning on the date described in subsection (a) and ending on the date described in subparagraph (B).

''(B) SUBSEQUENT STANDARDS.—The e-liquid manufacturing standards of the American National Standards Institute (including any revision to such standards made in accordance with paragraph (3)) apply to the introduction or delivery for introduction into interstate commerce of e-liquids beginning on the date of the adoption of such standards by the American National Standards Institute.

''(2) PERSONAL ELECTRONIC VAPORIZERS.—The manufacturing standards for personal electronic

vaporizers under this subsection shall consist of the following:

"(A) BATTERY SAFETY.—Any battery used in a personal electronic vaporizer shall conform to the IEC 62133 standards of the International Electrotechnical Commission, as in effect on the date of enactment of the Cigarette Smoking Reduction and Electronic Vapor Alternatives Act of 2017 and including any revision to such standards made in accordance with paragraph (3).

"(B) SHORT CIRCUIT PROTECTION.—A personal electronic vaporizer shall have a mechanism to ensure user and battery safety in the event of a short circuit of the heating element.

"(C) DISCHARGE MONITORING.—A rechargeable personal electronic vaporizer shall have a mechanism to prevent the battery from being discharged below a safe voltage during use or discharged faster than the battery can sustain safely.

"(D) CHARGE MONITORING.—A personal electronic vaporizer that contains an onboard charger shall include circuitry to monitor the battery voltage and charge current and limit

these to safe levels. A personal electronic vaporizer that contains multiple battery cells in series shall monitor the cells individually.

''(E) SERIAL AND LOT NUMBERS.—A personal electronic vaporizer shall include a serial or lot number on the label that allows the vaporizer to be traced to its time and place of manufacture. Notwithstanding the preceding sentence, a single-use personal electronic vaporizer may have such serial or lot number on the packaging of the vaporizer other than the label.

''(F) VERIFICATION AND VALIDATION.—A personal electronic vaporizer shall be constructed with sufficiently validated processes, or subject to sufficient verification and testing, to ensure that each individual vaporizer conforms to its specifications.

''(G) TRACKING AND RECALLS.—The manufacturer of a personal electronic vaporizer shall record all shipments of one or more personal electronic vaporizers by the manufacturer to a distributor, retailer, or end user, and correlate each such shipment to serial or lot numbers, to enable batch tracking and recalls.

''(H) MATERIALS.—The manufacturer of a personal electronic vaporizer shall ensure that—

''(i) materials that come in contact with e-liquids or vapor during manufacture or reasonably foreseeable use of the personal electronic vaporizer are limited to approved medical or food contact grade products with established safety and biocompatibility characteristics; and

''(ii) components of a personal electronic vaporizer which are expected to be subject to heat are appropriate for the expected temperatures.

''(3) REVISIONS.—Before issuing a revision to the standards applicable under paragraph (1)(A), (1)(B), or (2)(A), the American E-Liquid Manufacturing Standards Association, the American National Standards Institute, or the International Electrotechnical Commission, as applicable, shall notify the Secretary in writing of the proposed revision. Not later than 90 days after the date of receipt of such notice, the Secretary shall determine whether the proposed revision enhances the safety and quality of e-liquid products or personal electronic vaporizers, as applicable. If the Secretary determines that

the proposed revision does enhance the safety and quality of e-liquid products or personal electronic vaporizers, as applicable, the Secretary shall give notice of such determination to the public for a period of 90 days and, effective at the end of such period, incorporate the revision into the standards applicable under paragraph (1)(A), (1)(B), or (2)(A), as applicable.

''(c) CERTIFICATION OF COMPLIANCE WITH MANUFACTURING STANDARDS.—Beginning not later than 1 year after the date of enactment of the Cigarette Smoking Reduction and Electronic Vapor Alternatives Act of 2017, each e-liquid and personal electronic vaporizer manufacturer offering e-liquids for sale in interstate commerce shall have in effect a certification filed with the Secretary in writing that all such e-liquids or personal electronic vaporizers, as applicable, are manufactured, labeled, and otherwise in compliance with the standards under subsection (b).

''(d) INSPECTIONS FOR COMPLIANCE WITH MANUFACTURING STANDARDS.—E-liquid and personal electronic vaporizer manufacturers shall provide the Secretary with access to their facilities used in manufacturing e-liquids or personal electronic vaporizers, as applicable, for inspection.

''(e) FAILURE TO COMPLY WITH MANUFACTURING STANDARDS.—

''(1) IN GENERAL.—If the Secretary finds that an e-liquid or personal electronic vaporizer manufacturer is in noncompliance with the standards under subsection (b)—

''(A) the Secretary shall not take any enforcement action based on such noncompliance unless—

''(i) the Secretary gives the manufacturer notice of, and a period of 90 days to correct, such noncompliance; and

''(ii) the manufacturer fails, by the end of such 90-day period, to correct such noncompliance; and

''(B) if the manufacturer fails to correct such noncompliance, as described in paragraph (1)(A)(ii), the Secretary may issue an order requiring the manufacturer—

''(i) to suspend any commercial activity that the Secretary finds to be in noncompliance; and

''(ii) to not resume such activity until the manufacturer demonstrates to the Sec-

retary's satisfaction that such noncompliance has been corrected.

"(2) IMMEDIATE DANGER TO PUBLIC HEALTH.—Notwithstanding paragraph (1), if the Secretary determines that an e-liquid or personal electronic vaporizer manufacturer is in noncompliance with the standards under subsection (b), and that such noncompliance presents an immediate danger to public health, the Secretary may issue an order requiring the manufacturer to suspend production of such e-liquid or personal electronic vaporizer until the Secretary determines that such noncompliance is corrected.

"SEC. 1005. PROHIBITION AGAINST ADVERTISING OR PROMOTING TO MINORS.

"(a) PROHIBITION.—The Secretary may by regulation prohibit any manufacturer of an e-liquid or personal electronic vaporizer from advertising or promoting the e-liquid or personal electronic vaporizer to individuals who have not attained 18 years of age.

"(b) PENALTY.—If a manufacturer violates a prohibition established under subsection (a), the Secretary may refuse to accept for filing or renewal, and may revoke, the manufacturer's certification under section 1004(c).

"SEC. 1006. PREEMPTION OF CERTAIN STATE AND LOCAL REQUIREMENTS.

''(a) IN GENERAL.—No State or political subdivision of a State may establish or continue in effect any requirement with respect to the manufacture, warning requirements, marketing, distribution, or sale of an e-liquid or personal electronic vaporizer which is different from, or in addition to, any requirement under the provisions of this chapter or pursuant to section 503(g), including the exclusion of e-liquids and personal electronic vaporizers from the definition of a tobacco product under section 201.

''(b) EXCEPTION.—Information disclosed to a State consistent with subsection (a) that is exempt from disclosure under section 552(b)(4) of title 5, United States Code, shall be treated as a trade secret and confidential information by the State.

"SEC. 1007. OFFICE FOR E-LIQUID AND PERSONAL ELECTRONIC VAPORIZER STANDARDS COMPLIANCE.

''Not later than 90 days after the date of enactment of the Cigarette Smoking Reduction and Electronic Vapor Alternatives Act of 2017, the Secretary shall establish within the Food and Drug Administration's Center for Tobacco Products and Tobacco Harm Reduction an Office

of E-Liquid and Personal Electronic Vaporizer Standards Compliance. The Office shall—

''(1) be responsible for the implementation of this chapter and related matters assigned by the Director of such Center; and

''(2) provide technical and other nonfinancial assistance to e-liquid and personal electronic vaporizer manufacturers to assist them in complying with the requirements of this Act.''.

SEC. 5. JOINT COMPARATIVE HEALTH RISK ASSESSMENT.

Chapter X of the Federal Food, Drug, and Cosmetic Act, as added by section 4, is further amended by adding at the end the following:

''SEC. 1008. TOBACCO PRODUCTS AND NICOTINE DELIVERY ALTERNATIVES: COMPARATIVE HEALTH RISK ASSESSMENT.

''(a) ASSESSMENT.—The Secretary shall undertake a tobacco products and other nicotine delivery alternatives comparative health risk assessment and rank each category of products on a scale according to the reasonable expectation for morbidity and mortality risk when compared to smoking cigarettes based on laboratory studies and existing scientific data. For purposes of such assessment, tobacco and nicotine delivery alternative product categories shall include at a minimum—

''(1) cigarettes;

''(2) loose tobacco for roll-your-own tobacco products;

''(3) little cigars;

''(4) cigars;

''(5) pipe tobacco;

''(6) moist snuff;

''(7) dry snuff;

''(8) chewing tobacco;

''(9) snus;

''(10) vaporized tobacco, meaning 'heat not burn' technology intended for inhalation;

''(11) vapor produced by a personalized electronic vaporizer containing e-liquid with nicotine;

''(12) shisha and other tobacco products that are heated and inhaled via a hookah, water pipe, or other type of pipe (treated collectively as a single category);

''(13) dissolvable, chewable, drinkable, and other tobacco and nicotine products intended for oral ingestion (treated collectively as a single category);

''(14) tobacco and nicotine skin creams, patches, and other tobacco and nicotine products intended for transdermal consumption (treated collectively as a single category);

''(15) tobacco and nicotine sprays, droplets, and mists intended for nasal consumption (treated as a single category); and

''(16) other nicotine-containing products (treated collectively as a single category).

''(b) REPORT.—Not later than 18 months after the date of enactment of the Cigarette Smoking Reduction and Electronic Vapor Alternatives Act of 2017, the Secretary shall report to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate on the results of the comparative health risk assessment under subsection (a). Based on such results, such report shall include recommendations on—

''(1) new or improved tobacco harm reduction strategies; and

''(2) the possible need for additional legislative authorities to implement such strategies.''.

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