

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

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.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

1 **SECTION 1. SHORT TITLE; TABLE OF CONTENTS.**

2 (a) SHORT TITLE.—This Act may be cited as the
3 “Cigarette Smoking Reduction and Electronic Vapor Al-
4 ternatives Act of 2017”.

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

Sec. 1. Short title; table of contents.

Sec. 2. Findings.

Sec. 3. Purposes of the Family Smoking Prevention and Tobacco Control Act.

Sec. 4. Regulation of electronic vapor products.

Sec. 5. Joint comparative health risk assessment.

7 **SEC. 2. FINDINGS.**

8 The Congress finds the following:

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

13 (A) the burning of tobacco produces a
14 chemical mixture of more than 7,000 com-
15 pounds;

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

20 (C) cigarette smoking causes more than
21 480,000 deaths each year, including nearly
22 42,000 deaths due to secondhand tobacco
23 smoke;

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

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

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

13 (3) Evidence from numerous studies strongly
14 suggests that electronic vapor products are mag-
15 nitudes safer than traditional, combustible ciga-
16 rettes. Studies have found that several million reg-
17 ular vapers in the United States no longer regularly
18 smoke cigarettes.

19 (4) Studies of cigarette smokers who switched
20 to vapor found significant improvements in lung
21 function, including a study finding asthmatic smok-
22 ers who switched to vapor had significant improve-
23 ments in spirometry data, asthma control, airway
24 hyperresponsiveness, and lower blood pressure.

1 (5) The Royal College of Physicians 2016 re-
2 port on e-cigarettes titled, “Nicotine without smoke:
3 Tobacco harm reduction” issued the following find-
4 ings:

5 (A) The available evidence to date indi-
6 cates that e-cigarettes are being used almost ex-
7 clusively as safer alternatives to smoked to-
8 bacco, by confirmed smokers who are trying to
9 reduce harm to themselves or others from
10 smoking, or to quit smoking completely.

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

15 (C) E-cigarettes are marketed as consumer
16 products and are proving much more popular
17 than Food and Drug Administration-approved
18 nicotine replacement therapies (NRT) as a sub-
19 stitute and competitor for tobacco cigarettes.

20 (6) “E-liquid” is the liquid that is heated into
21 vapor. It contains, principally, propylene glycol, veg-
22 etable glycerin, in some cases food flavoring, in some
23 cases nicotine, and in some cases water; propylene
24 glycol and vegetable glycerin are designated as “gen-

1 erally recognized as safe” by the Food and Drug Ad-
2 ministration (FDA) as food additives.

3 (7) Surveys have found that a significant ma-
4 jority of regular users of electronic vapor products
5 had previously tried FDA-approved smoking ces-
6 sation drugs to quit smoking without success.

7 (8) An expert independent evidence review pub-
8 lished by Public Health England (PHE) concluded
9 that—

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

12 (B) nearly half the population doesn’t real-
13 ize vapor is much less harmful than smoking;
14 and

15 (C) there is no evidence suggesting elec-
16 tronic vapor products act as a route into smok-
17 ing for children or nonsmokers.

18 (9) Electronic vapor product sales in the United
19 States have increased from an estimated \$100 mil-
20 lion in 2010 to \$4 billion in 2016 while cigarette
21 consumption in the United States declined from
22 \$307 billion in 2010 to an estimated \$265 billion in
23 2016.

24 (10) On May 10, 2016, the Food and Drug Ad-
25 ministration issued its “Deeming Regulation” to

1 deem e-cigarettes or electronic vapor products to be
2 subject to its authority. The regulation will, as a
3 practical matter, because of its significant compli-
4 ance costs and poorly articulated standard for pro-
5 tecting public health, ban the sale of all electronic
6 vapor products by August 2018.

7 (11) The Food and Drug Administration’s
8 Deeming Regulation, by effectively banning elec-
9 tronic vapor products, will push vapers who have
10 quit or reduced cigarette smoking by switching to
11 electronic vapor products back to smoking deadly
12 cigarettes.

13 (12) The 2015 Monitoring the Future survey of
14 the National Institute on Drug Abuse found past-
15 30-day use of an electronic vapor product by 8th,
16 10th, and 12th graders combined declined from 13.9
17 percent in 2014 to 9.9 percent in 2016; however,
18 that survey found that fewer than 20 percent of
19 teens who used an electronic vapor product in the
20 past 30 days reported using a product containing
21 nicotine.

22 (13) Electronic vapor products show tremen-
23 dous promise in reducing cigarette smoking, and cig-
24 arette smoking attributable morbidity, mortality,
25 and health care costs.

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

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

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

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

21 “(9) to promote—

22 “(A) cessation to reduce disease risk and
 23 the social costs associated with tobacco-related
 24 diseases; and

25 “(B) harm reduction strategies; and”.

1 **SEC. 4. REGULATION OF ELECTRONIC VAPOR PRODUCTS.**

2 (a) CENTER FOR TOBACCO PRODUCTS AND TOBACCO
3 HARM REDUCTION.—Section 901(e) of the Federal Food,
4 Drug, and Cosmetic Act (21 U.S.C. 387a(e)) is amend-
5 ed—

6 (1) in the subsection heading, by striking
7 “CENTER FOR TOBACCO PRODUCTS” and inserting
8 “CENTER FOR TOBACCO PRODUCTS AND TOBACCO
9 HARM REDUCTION”;

10 (2) by striking “Center for Tobacco Products”
11 and inserting “Center for Tobacco Products and To-
12 bacco Harm Reduction”; and

13 (3) by striking “this chapter” and inserting
14 “this chapter and chapter X”.

15 (b) FDA AUTHORITY OVER ELECTRONIC VAPOR
16 PRODUCTS.—

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

21 (A) in paragraph (2), by inserting “an e-
22 liquid (as defined in section 1001), a personal
23 electronic vaporizer (as defined in section
24 1001),” before “or a combination product”; and

25 (B) in paragraph (3), by inserting after
26 “The products described in paragraph (2)” the

1 following: “(other than an e-liquid or personal
2 electronic vaporizer)”.

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

6 (A) in paragraph (1)—

7 (i) in subparagraph (A), by striking
8 “or biological product” and inserting “, bi-
9 ological product, e-liquid, or personal elec-
10 tronic vaporizer”; and

11 (ii) in subparagraph (D)—

12 (I) in clause (ii), by striking “or”
13 at the end;

14 (II) in clause (iii), by striking the
15 period at the end and inserting “; or”;
16 and

17 (III) by adding at the end the
18 following:

19 “(iv) an e-liquid or personal electronic vapor-
20 izer, the agency center charged with regulating e-liq-
21 uids and personal electronic vaporizers shall have
22 primary jurisdiction.”; and

23 (B) in paragraph (9)—

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

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

6 “(C) The terms ‘e-liquid’ and ‘personal elec-
7 tronic vaporizer’ have the meanings given to such
8 terms in section 1001.”.

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

12 (A) by redesignating chapter X as chapter
13 XI;

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

17 (C) in section 505(n)(2), by striking
18 “1004” and inserting “1104”;

19 (D) in sections 523(b)(2)(D) and
20 704(g)(13), by striking “1003(g)” and inserting
21 “1103(g)”;

22 (E) in section 1109(a)(5)(A), as redesign-
23 ated by paragraph (4), by striking “1008”
24 and inserting “1108”; and

1 (F) by inserting after chapter IX the fol-
2 lowing:

3 **“CHAPTER X—ELECTRONIC VAPOR**
4 **PRODUCTS**

5 **“SEC. 1001. DEFINITIONS.**

6 “In this chapter:

7 “(1) The term ‘e-liquid’ means any liquid solu-
8 tion that—

9 “(A) may or may not contain nicotine; and

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

14 “(2) The term ‘personal electronic vaporizer’
15 means an electronic device that employs a heating
16 element or atomizer that converts an e-liquid into an
17 aerosol, vapor, or vapor-like mist through a non-
18 combustive process.

19 “(3) The terms ‘e-liquid’ and ‘personal elec-
20 tronic vaporizer’ exclude—

21 “(A) a drug as defined in section
22 201(g)(1);

23 “(B) a device as defined in section 201(h);
24 and

1 “(C) a biological product as defined in sec-
2 tion 351 of the Public Health Service Act.

3 **“SEC. 1002. EXCLUSIVE AUTHORITY FOR REGULATING E-**
4 **LIQUIDS AND PERSONAL ELECTRONIC VA-**
5 **PORIZERS.**

6 “The authorities vested by this chapter constitute the
7 exclusive authorities of the Secretary to regulate e-liquids
8 and personal electronic vaporizers, except to the extent e-
9 liquids and personal electronic vaporizers are within com-
10 bination products regulated pursuant to section 503(g).

11 **“SEC. 1003. PROHIBITED ACTS; PENALTIES.**

12 “(a) PROHIBITIONS.—

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

15 “(A) The sale of an electronic vapor prod-
16 uct or e-liquid to any person younger than 18
17 years of age.

18 “(B) The manufacture of an e-liquid or
19 personal electronic vaporizer in noncompliance
20 with the standards under section 1004(b) in
21 violation of an order issued under section
22 1004(e).

23 “(C) The offering of e-liquids or personal
24 electronic vaporizers for sale in interstate com-
25 merce 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

1 not have a certification in effect as required by sec-
2 tion 1004(c).

3 “(c) MISBRANDING.—An e-liquid or personal elec-
4 tronic vaporizer shall be treated as misbranded if its label-
5 ing (as such term is defined in section 201 with respect
6 to drugs) is in noncompliance with the standards under
7 section 1004(b) in violation of an order issued under sec-
8 tion 1004(e).

9 “(d) PENALTIES.—Any person who violates a provi-
10 sion of subsection (a) shall be imprisoned not more than
11 3 years, fined not more than \$10,000 (notwithstanding
12 section 3571(e) of title 18, United States Code) for each
13 day on which the violation continues, or both.

14 **“SEC. 1004. STANDARDS FOR THE MANUFACTURING OF E-**
15 **LIQUIDS AND PERSONAL ELECTRONIC VA-**
16 **PORIZERS; COMPLIANCE.**

17 “(a) REQUIREMENT.—Beginning on the date that is
18 1 year after the date of enactment of the Cigarette Smok-
19 ing Reduction and Electronic Vapor Alternatives Act of
20 2017, any e-liquid or personal electronic vaporizer intro-
21 duced or delivered for introduction into interstate com-
22 merce shall conform to the e-liquid or personal electronic
23 vaporizer (as applicable) manufacturing standards under
24 subsection (b), including the labeling standards therein.

25 “(b) MANUFACTURING STANDARDS.—

1 “(1) E-LIQUIDS.—The manufacturing stand-
2 ards for e-liquids under this subsection shall consist
3 of the following:

4 “(A) INTERIM STANDARDS.—The e-liquid
5 manufacturing standards issued by the Amer-
6 ican E-Liquid Manufacturing Standards Asso-
7 ciation (version 2.3.2) on March 8, 2017 (in-
8 cluding any revision to such standards made in
9 accordance with paragraph (3)), apply to the
10 introduction or delivery for introduction into
11 interstate commerce of e-liquids during the pe-
12 riod beginning on the date described in sub-
13 section (a) and ending on the date described in
14 subparagraph (B).

15 “(B) SUBSEQUENT STANDARDS.—The e-
16 liquid manufacturing standards of the American
17 National Standards Institute (including any re-
18 vision to such standards made in accordance
19 with paragraph (3)) apply to the introduction
20 or delivery for introduction into interstate com-
21 merce of e-liquids beginning on the date of the
22 adoption of such standards by the American
23 National Standards Institute.

24 “(2) PERSONAL ELECTRONIC VAPORIZERS.—
25 The manufacturing standards for personal electronic

1 vaporizers under this subsection shall consist of the
2 following:

3 “(A) BATTERY SAFETY.—Any battery used
4 in a personal electronic vaporizer shall conform
5 to the IEC 62133 standards of the Inter-
6 national Electrotechnical Commission, as in ef-
7 fect on the date of enactment of the Cigarette
8 Smoking Reduction and Electronic Vapor Alter-
9 natives Act of 2017 and including any revision
10 to such standards made in accordance with
11 paragraph (3).

12 “(B) SHORT CIRCUIT PROTECTION.—A
13 personal electronic vaporizer shall have a mech-
14 anism to ensure user and battery safety in the
15 event of a short circuit of the heating element.

16 “(C) DISCHARGE MONITORING.—A re-
17 chargeable personal electronic vaporizer shall
18 have a mechanism to prevent the battery from
19 being discharged below a safe voltage during
20 use or discharged faster than the battery can
21 sustain safely.

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

1 these to safe levels. A personal electronic vapor-
2 izer that contains multiple battery cells in series
3 shall monitor the cells individually.

4 “(E) SERIAL AND LOT NUMBERS.—A per-
5 sonal electronic vaporizer shall include a serial
6 or lot number on the label that allows the va-
7 porizer to be traced to its time and place of
8 manufacture. Notwithstanding the preceding
9 sentence, a single-use personal electronic vapor-
10 izer may have such serial or lot number on the
11 packaging of the vaporizer other than the label.

12 “(F) VERIFICATION AND VALIDATION.—A
13 personal electronic vaporizer shall be con-
14 structed with sufficiently validated processes, or
15 subject to sufficient verification and testing, to
16 ensure that each individual vaporizer conforms
17 to its specifications.

18 “(G) TRACKING AND RECALLS.—The man-
19 ufacturer of a personal electronic vaporizer
20 shall record all shipments of one or more per-
21 sonal electronic vaporizers by the manufacturer
22 to a distributor, retailer, or end user, and cor-
23 relate each such shipment to serial or lot num-
24 bers, to enable batch tracking and recalls.

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

3 “(i) materials that come in contact
4 with e-liquids or vapor during manufacture
5 or reasonably foreseeable use of the per-
6 sonal electronic vaporizer are limited to ap-
7 proved medical or food contact grade prod-
8 ucts with established safety and biocompat-
9 ibility characteristics; and

10 “(ii) components of a personal elec-
11 tronic vaporizer which are expected to be
12 subject to heat are appropriate for the ex-
13 pected temperatures.

14 “(3) REVISIONS.—Before issuing a revision to
15 the standards applicable under paragraph (1)(A),
16 (1)(B), or (2)(A), the American E-Liquid Manufac-
17 turing Standards Association, the American Na-
18 tional Standards Institute, or the International Elec-
19 trotechnical Commission, as applicable, shall notify
20 the Secretary in writing of the proposed revision.
21 Not later than 90 days after the date of receipt of
22 such notice, the Secretary shall determine whether
23 the proposed revision enhances the safety and qual-
24 ity of e-liquid products or personal electronic vapor-
25 izers, as applicable. If the Secretary determines that

1 the proposed revision does enhance the safety and
2 quality of e-liquid products or personal electronic va-
3 porizers, as applicable, the Secretary shall give no-
4 tice of such determination to the public for a period
5 of 90 days and, effective at the end of such period,
6 incorporate the revision into the standards applicable
7 under paragraph (1)(A), (1)(B), or (2)(A), as appli-
8 cable.

9 “(c) CERTIFICATION OF COMPLIANCE WITH MANU-
10 FACTURING STANDARDS.—Beginning not later than 1
11 year after the date of enactment of the Cigarette Smoking
12 Reduction and Electronic Vapor Alternatives Act of 2017,
13 each e-liquid and personal electronic vaporizer manufac-
14 turer offering e-liquids for sale in interstate commerce
15 shall have in effect a certification filed with the Secretary
16 in writing that all such e-liquids or personal electronic va-
17 porizers, as applicable, are manufactured, labeled, and
18 otherwise in compliance with the standards under sub-
19 section (b).

20 “(d) INSPECTIONS FOR COMPLIANCE WITH MANU-
21 FACTURING STANDARDS.—E-liquid and personal elec-
22 tronic vaporizer manufacturers shall provide the Secretary
23 with access to their facilities used in manufacturing e-liq-
24 uids or personal electronic vaporizers, as applicable, for
25 inspection.

1 “(e) FAILURE TO COMPLY WITH MANUFACTURING
2 STANDARDS.—

3 “(1) IN GENERAL.—If the Secretary finds that
4 an e-liquid or personal electronic vaporizer manufac-
5 turer is in noncompliance with the standards under
6 subsection (b)—

7 “(A) the Secretary shall not take any en-
8 forcement action based on such noncompliance
9 unless—

10 “(i) the Secretary gives the manufac-
11 turer notice of, and a period of 90 days to
12 correct, such noncompliance; and

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

16 “(B) if the manufacturer fails to correct
17 such noncompliance, as described in paragraph
18 (1)(A)(ii), the Secretary may issue an order re-
19 quiring the manufacturer—

20 “(i) to suspend any commercial activ-
21 ity that the Secretary finds to be in non-
22 compliance; and

23 “(ii) to not resume such activity until
24 the manufacturer demonstrates to the Sec-

1 retary’s satisfaction that such noncompli-
2 ance has been corrected.

3 “(2) IMMEDIATE DANGER TO PUBLIC
4 HEALTH.—Notwithstanding paragraph (1), if the
5 Secretary determines that an e-liquid or personal
6 electronic vaporizer manufacturer is in noncompli-
7 ance with the standards under subsection (b), and
8 that such noncompliance presents an immediate dan-
9 ger to public health, the Secretary may issue an
10 order requiring the manufacturer to suspend produc-
11 tion of such e-liquid or personal electronic vaporizer
12 until the Secretary determines that such noncompli-
13 ance is corrected.

14 **“SEC. 1005. PROHIBITION AGAINST ADVERTISING OR PRO-**
15 **MOTING TO MINORS.**

16 “(a) PROHIBITION.—The Secretary may by regula-
17 tion prohibit any manufacturer of an e-liquid or personal
18 electronic vaporizer from advertising or promoting the e-
19 liquid or personal electronic vaporizer to individuals who
20 have not attained 18 years of age.

21 “(b) PENALTY.—If a manufacturer violates a prohi-
22 bition established under subsection (a), the Secretary may
23 refuse to accept for filing or renewal, and may revoke, the
24 manufacturer’s certification under section 1004(c).

1 **“SEC. 1006. PREEMPTION OF CERTAIN STATE AND LOCAL**
2 **REQUIREMENTS.**

3 “(a) IN GENERAL.—No State or political subdivision
4 of a State may establish or continue in effect any require-
5 ment with respect to the manufacture, warning require-
6 ments, marketing, distribution, or sale of an e-liquid or
7 personal electronic vaporizer which is different from, or
8 in addition to, any requirement under the provisions of
9 this chapter or pursuant to section 503(g), including the
10 exclusion of e-liquids and personal electronic vaporizers
11 from the definition of a tobacco product under section
12 201.

13 “(b) EXCEPTION.—Information disclosed to a State
14 consistent with subsection (a) that is exempt from disclo-
15 sure under section 552(b)(4) of title 5, United States
16 Code, shall be treated as a trade secret and confidential
17 information by the State.

18 **“SEC. 1007. OFFICE FOR E-LIQUID AND PERSONAL ELEC-**
19 **TRONIC VAPORIZER STANDARDS COMPLI-**
20 **ANCE.**

21 “Not later than 90 days after the date of enactment
22 of the Cigarette Smoking Reduction and Electronic Vapor
23 Alternatives Act of 2017, the Secretary shall establish
24 within the Food and Drug Administration’s Center for To-
25 bacco Products and Tobacco Harm Reduction an Office

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

3 “(1) be responsible for the implementation of
 4 this chapter and related matters assigned by the Di-
 5 rector of such Center; and

6 “(2) provide technical and other nonfinancial
 7 assistance to e-liquid and personal electronic vapor-
 8 izer manufacturers to assist them in complying with
 9 the requirements of this Act.”.

10 **SEC. 5. JOINT COMPARATIVE HEALTH RISK ASSESSMENT.**

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

14 **“SEC. 1008. TOBACCO PRODUCTS AND NICOTINE DELIVERY**
 15 **ALTERNATIVES: COMPARATIVE HEALTH RISK**
 16 **ASSESSMENT.**

17 “(a) ASSESSMENT.—The Secretary shall undertake a
 18 tobacco products and other nicotine delivery alternatives
 19 comparative health risk assessment and rank each cat-
 20 egory of products on a scale according to the reasonable
 21 expectation for morbidity and mortality risk when com-
 22 pared to smoking cigarettes based on laboratory studies
 23 and existing scientific data. For purposes of such assess-
 24 ment, tobacco and nicotine delivery alternative product
 25 categories shall include at a minimum—

1 “(1) cigarettes;

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

4 “(3) little cigars;

5 “(4) cigars;

6 “(5) pipe tobacco;

7 “(6) moist snuff;

8 “(7) dry snuff;

9 “(8) chewing tobacco;

10 “(9) snus;

11 “(10) vaporized tobacco, meaning ‘heat not
12 burn’ technology intended for inhalation;

13 “(11) vapor produced by a personalized elec-
14 tronic vaporizer containing e-liquid with nicotine;

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

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

22 “(14) tobacco and nicotine skin creams, patch-
23 es, and other tobacco and nicotine products intended
24 for transdermal consumption (treated collectively as
25 a single category);

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

4 “(16) other nicotine-containing products (treat-
5 ed collectively as a single category).

6 “(b) REPORT.—Not later than 18 months after the
7 date of enactment of the Cigarette Smoking Reduction
8 and Electronic Vapor Alternatives Act of 2017, the Sec-
9 retary shall report to the Committee on Energy and Com-
10 merce of the House of Representatives and the Committee
11 on Health, Education, Labor, and Pensions of the Senate
12 on the results of the comparative health risk assessment
13 under subsection (a). Based on such results, such report
14 shall include recommendations on—

15 “(1) new or improved tobacco harm reduction
16 strategies; and

17 “(2) the possible need for additional legislative
18 authorities to implement such strategies.”.

○