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(Original Signature of Member)

115TH CONGRESS
1ST SESSION

H. R. _____

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

Mr. HUNTER introduced the following bill; which was referred to the
Committee on _____

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 \$3.5 billion in 2015 while cigarette
21 consumption in the United States declined from
22 \$307 billion in 2010 to an estimated \$265 billion in
23 2015.

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 13.2 percent in 2015; 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) Since the Food and Drug Administration
2 was granted authority to regulate tobacco products
3 in 2009, the agency has failed to grant market ap-
4 proval to any modified risk tobacco product.

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

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

10 “(9) to promote—

11 “(A) cessation to reduce disease risk and
12 the social costs associated with tobacco-related
13 diseases; and

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

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

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

20 (1) in the subsection heading, by striking
21 “CENTER FOR TOBACCO PRODUCTS” and inserting
22 “CENTER FOR TOBACCO PRODUCTS AND TOBACCO
23 HARM REDUCTION”;

1 (2) by striking “Center for Tobacco Products”
2 and inserting “Center for Tobacco Products and To-
3 bacco Harm Reduction”; and

4 (3) by striking “this chapter” and inserting
5 “this chapter and chapter X”.

6 (b) FDA AUTHORITY OVER ELECTRONIC VAPOR
7 PRODUCTS.—

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

12 (A) in paragraph (2), by inserting “an e-
13 liquid (as defined in section 1001), a personal
14 electronic vaporizer (as defined in section
15 1001),” before “or a combination product”; and

16 (B) in paragraph (3), by inserting after
17 “The products described in paragraph (2)” the
18 following: “(other than an e-liquid or personal
19 electronic vaporizer)”.

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

23 (A) in paragraph (1)—

24 (i) in subparagraph (A), by striking
25 “or biological product” and inserting “, bi-

1 logical product, e-liquid, or personal elec-
2 tronic vaporizer”; and

3 (ii) in subparagraph (D)—

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

6 (II) in clause (iii), by striking the
7 period at the end and inserting “; or”;
8 and

9 (III) by adding at the end the
10 following:

11 “(iv) an e-liquid or personal electronic vapor-
12 izer, the agency center charged with regulating e-liq-
13 uids and personal electronic vaporizers shall have
14 primary jurisdiction.”; and

15 (B) in paragraph (9)—

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

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

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

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

4 (A) by redesignating chapter X as chapter
5 XI;

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

9 (C) in section 505(n)(2), by striking
10 “1004” and inserting “1104”;

11 (D) in sections 523(b)(2)(D) and
12 704(g)(13), by striking “1003(g)” and inserting
13 “1103(g)”;

14 (E) in section 1109(a)(5)(A), as redesign-
15 nated by paragraph (4), by striking “1008”
16 and inserting “1108”; and

17 (F) by inserting after chapter IX the fol-
18 lowing:

19 **“CHAPTER X—ELECTRONIC VAPOR**
20 **PRODUCTS**

21 **“SEC. 1001. DEFINITIONS.**

22 “In this chapter:

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

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

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

5 “(2) The term ‘personal electronic vaporizer’
6 means an electronic device that employs a heating
7 element or atomizer that converts an e-liquid into an
8 aerosol, vapor, or vapor-like mist through a non-
9 combustive process.

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

12 “(A) a drug as defined in section
13 201(g)(1);

14 “(B) a device as defined in section 201(h);
15 and

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

18 **“SEC. 1002. EXCLUSIVE AUTHORITY FOR REGULATING E-
19 LIQUIDS AND PERSONAL ELECTRONIC VA-
20 PORIZERS.**

21 “The authorities vested by this chapter constitute the
22 exclusive authorities of the Secretary to regulate e-liquids
23 and personal electronic vaporizers, except to the extent e-
24 liquids and personal electronic vaporizers are within com-
25 bination products regulated pursuant to section 503(g).

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

2 “(a) PROHIBITIONS.—The following acts and the
3 causing thereof are hereby prohibited:

4 “(1) The manufacture of an e-liquid or personal
5 electronic vaporizer in noncompliance with the
6 standards under section 1004(b) in violation of an
7 order issued under section 1004(e).

8 “(2) The offering of e-liquids or personal elec-
9 tronic vaporizers for sale in interstate commerce by
10 an e-liquid or personal electronic vaporizer manufac-
11 turer that does not have a certification in effect as
12 required by section 1004(e).

13 “(3) The failure by an e-liquid or personal elec-
14 tronic vaporizer manufacturer to provide access for
15 inspection as required by section 1004(d).

16 “(4)(A) The introduction or delivery for intro-
17 duction in interstate commerce of an e-liquid or per-
18 sonal electronic vaporizer by any person that is adul-
19 terated or misbranded, as described in subsection (b)
20 or (c) respectively.

21 “(B) Notwithstanding subparagraph (A), a re-
22 tailer may be found to be in violation of such sub-
23 paragraph with respect to the introduction or deliv-
24 ery for introduction in interstate commerce of an e-
25 liquid or personal electronic vaporizer at retail only
26 if the violation occurs knowingly.

1 “(b) ADULTERATION.—An e-liquid or personal elec-
2 tronic vaporizer shall be treated as adulterated if—

3 “(1) it was manufactured in noncompliance
4 with the standards under section 1004(b) in viola-
5 tion of an order issued under section 1004(e); or

6 “(2) it was manufactured by an e-liquid or per-
7 sonal electronic vaporizer manufacturer that does
8 not have a certification in effect as required by sec-
9 tion 1004(c).

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

16 “(d) PENALTIES.—An e-liquid or personal electronic
17 vaporizer manufacturer who violates a provision of sub-
18 section (a) shall be imprisoned not more than 3 years,
19 fined not more than \$10,000 (notwithstanding section
20 3571(e) of title 18, United States Code) for each day on
21 which the violation continues, or both.

1 **“SEC. 1004. STANDARDS FOR THE MANUFACTURING OF E-**
2 **LIQUIDS AND PERSONAL ELECTRONIC VA-**
3 **PORIZERS; COMPLIANCE.**

4 “(a) REQUIREMENT.—Beginning on the date that is
5 1 year after the date of enactment of the Cigarette Smok-
6 ing Reduction and Electronic Vapor Alternatives Act of
7 2017, any e-liquid or personal electronic vaporizer intro-
8 duced or delivered for introduction into interstate com-
9 merce shall conform to the e-liquid or personal electronic
10 vaporizer (as applicable) manufacturing standards under
11 subsection (b), including the labeling standards therein.

12 “(b) MANUFACTURING STANDARDS.—

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

16 “(A) INTERIM STANDARDS.—The e-liquid
17 manufacturing standards issued by the Amer-
18 ican E-Liquid Manufacturing Standards Asso-
19 ciation (version 2.3.) on January 13, 2016 (in-
20 cluding any revision to such standards made in
21 accordance with paragraph (3)) apply to the in-
22 troduction or delivery for introduction into
23 interstate commerce of e-liquids during the pe-
24 riod beginning on the date described in sub-
25 section (a) and ending on the date described in
26 subparagraph (B).

1 “(B) SUBSEQUENT STANDARDS.—The e-
2 liquid manufacturing standards of the American
3 National Standards Institute (including any re-
4 vision to such standards made in accordance
5 with paragraph (3)) apply to the introduction
6 or delivery for introduction into interstate com-
7 merce of e-liquids beginning on the date of the
8 adoption of such standards by the American
9 National Standards Institute.

10 “(2) PERSONAL ELECTRONIC VAPORIZERS.—
11 The manufacturing standards for personal electronic
12 vaporizers under this subsection shall consist of the
13 following:

14 “(A) BATTERY SAFETY.—Any battery used
15 in a personal electronic vaporizer shall conform
16 to the IEC 62133 standards of the Inter-
17 national Electrotechnical Commission, as in ef-
18 fect on the date of enactment of the Cigarette
19 Smoking Reduction and Electronic Vapor Alter-
20 natives Act of 2017 and including any revision
21 to such standards made in accordance with
22 paragraph (3).

23 “(B) SHORT CIRCUIT PROTECTION.—A
24 personal electronic vaporizer shall have a mech-

1 anism to ensure user and battery safety in the
2 event of a short circuit of the heating element.

3 “(C) DISCHARGE MONITORING.—A re-
4 chargeable personal electronic vaporizer shall
5 have a mechanism to prevent the battery from
6 being discharged below a safe voltage during
7 use or discharged faster than the battery can
8 sustain safely.

9 “(D) CHARGE MONITORING.—A personal
10 electronic vaporizer that contains an onboard
11 charger shall include circuitry to monitor the
12 battery voltage and charge current and limit
13 these to safe levels. A personal electronic vapor-
14 izer that contains multiple battery cells in series
15 shall monitor the cells individually.

16 “(E) SERIAL AND LOT NUMBERS.—A per-
17 sonal electronic vaporizer shall include a serial
18 or lot number on the label that allows the va-
19 porizer to be traced to its time and place of
20 manufacture. Notwithstanding the preceding
21 sentence, a single-use personal electronic vapor-
22 izer may have such serial or lot number on the
23 packaging of the vaporizer other than the label.

24 “(F) VERIFICATION AND VALIDATION.—A
25 personal electronic vaporizer shall be con-

1 structured with sufficiently validated processes, or
2 subject to sufficient verification and testing, to
3 ensure that each individual vaporizer conforms
4 to its specifications.

5 “(G) TRACKING AND RECALLS.—The man-
6 ufacturer of a personal electronic vaporizer
7 shall record all shipments of one or more per-
8 sonal electronic vaporizers by the manufacturer
9 to a distributor, retailer, or end user, and cor-
10 relate each such shipment to serial or lot num-
11 bers, to enable batch tracking and recalls.

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

14 “(i) materials that come in contact
15 with e-liquids or vapor during manufacture
16 or reasonably foreseeable use of the per-
17 sonal electronic vaporizer are limited to ap-
18 proved medical or food contact grade prod-
19 ucts with established safety and biocompat-
20 ibility characteristics; and

21 “(ii) components of a personal elec-
22 tronic vaporizer which are expected to be
23 subject to heat are appropriate for the ex-
24 pected temperatures.

1 “(3) REVISIONS.—Before issuing a revision to
2 the standards applicable under paragraph (1)(A),
3 (1)(B), or (2)(A), the American E–Liquid Manufac-
4 turing Standards Association, the American Na-
5 tional Standards Institute, or the International Elec-
6 trotechnical Commission, as applicable, shall notify
7 the Secretary in writing of the proposed revision.
8 Not later than 90 days after the date of receipt of
9 such notice, the Secretary shall determine whether
10 the proposed revision enhances the safety and qual-
11 ity of e-liquid products or personal electronic vapor-
12 izers, as applicable. If the Secretary determines that
13 the proposed revision does enhance the safety and
14 quality of e-liquid products or personal electronic va-
15 porizers, as applicable, the Secretary shall give no-
16 tice of such determination to the public for a period
17 of 90 days and, effective at the end of such period,
18 incorporate the revision into the standards applicable
19 under paragraph (1)(A), (1)(B), or (2)(A), as appli-
20 cable.

21 “(c) CERTIFICATION OF COMPLIANCE WITH MANU-
22 FACTURING STANDARDS.—Beginning not later than 1
23 year after the date of enactment of the Cigarette Smoking
24 Reduction and Electronic Vapor Alternatives Act of 2017,
25 each e-liquid and personal electronic vaporizer manufac-

1 turer offering e-liquids for sale in interstate commerce
2 shall have in effect a certification filed with the Secretary
3 in writing that all such e-liquids or personal electronic va-
4 porizers, as applicable, are manufactured, labeled, and
5 otherwise in compliance with the standards under sub-
6 section (b).

7 “(d) INSPECTIONS FOR COMPLIANCE WITH MANU-
8 FACTURING STANDARDS.—E-liquid and personal elec-
9 tronic vaporizer manufacturers shall provide the Secretary
10 with access to their facilities used in manufacturing e-liq-
11 uids or personal electronic vaporizers, as applicable, for
12 inspection.

13 “(e) FAILURE TO COMPLY WITH MANUFACTURING
14 STANDARDS.—

15 “(1) IN GENERAL.—If the Secretary finds that
16 an e-liquid or personal electronic vaporizer manufac-
17 turer is in noncompliance with the standards under
18 subsection (b)—

19 “(A) the Secretary shall not take any en-
20 forcement action based on such noncompliance
21 unless—

22 “(i) the Secretary gives the manufac-
23 turer notice of, and a period of 90 days to
24 correct, such noncompliance; and

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

4 “(B) if the manufacturer fails to correct
5 such noncompliance, as described in paragraph
6 (1)(A)(ii), the Secretary may issue an order re-
7 quiring the manufacturer—

8 “(i) to suspend any commercial activ-
9 ity that the Secretary finds to be in non-
10 compliance; and

11 “(ii) to not resume such activity until
12 the manufacturer demonstrates to the Sec-
13 retary’s satisfaction that such noncompli-
14 ance has been corrected.

15 “(2) IMMEDIATE DANGER TO PUBLIC
16 HEALTH.—Notwithstanding paragraph (1), if the
17 Secretary determines that an e-liquid or personal
18 electronic vaporizer manufacturer is in noncompli-
19 ance with the standards under subsection (b), and
20 that such noncompliance presents an immediate dan-
21 ger to public health, the Secretary may issue an
22 order requiring the manufacturer to suspend produc-
23 tion of such e-liquid or personal electronic vaporizer
24 until the Secretary determines that such noncompli-
25 ance is corrected.

1 **“SEC. 1005. PROHIBITION AGAINST ADVERTISING OR PRO-**
2 **MOTING TO MINORS.**

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

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

12 **“SEC. 1006. PREEMPTION OF CERTAIN STATE AND LOCAL**
13 **REQUIREMENTS.**

14 “(a) IN GENERAL.—No State or political subdivision
15 of a State may establish or continue in effect any require-
16 ment with respect to the manufacture, distribution, or sale
17 of an e-liquid or personal electronic vaporizer which is dif-
18 ferent from, or in addition to, any requirement under the
19 provisions of this chapter or pursuant to section 503(g),
20 including the exclusion of e-liquids and personal electronic
21 vaporizers from the definition of a tobacco product under
22 section 201.

23 “(b) EXCEPTION.—Information disclosed to a State
24 consistent with subsection (a) that is exempt from disclo-
25 sure under section 552(b)(4) of title 5, United States

1 Code, shall be treated as a trade secret and confidential
2 information by the State.

3 **“SEC. 1007. OFFICE FOR E-LIQUID AND PERSONAL ELEC-**
4 **TRONIC VAPORIZER STANDARDS COMPLI-**
5 **ANCE.**

6 “Not later than 90 days after the date of enactment
7 of the Cigarette Smoking Reduction and Electronic Vapor
8 Alternatives Act of 2017, the Secretary shall establish
9 within the Food and Drug Administration’s Center for To-
10 bacco Products and Tobacco Harm Reduction an Office
11 of E–Liquid and Personal Electronic Vaporizer Standards
12 Compliance. The Office shall—

13 “(1) be responsible for the implementation of
14 this chapter and related matters assigned by the Di-
15 rector of such Center; and

16 “(2) provide technical and other nonfinancial
17 assistance to e-liquid and personal electronic vapor-
18 izer manufacturers to assist them in complying with
19 the requirements of this Act.”.

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

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

1 **“SEC. 1008. TOBACCO PRODUCTS AND NICOTINE DELIVERY**
2 **ALTERNATIVES: COMPARATIVE HEALTH RISK**
3 **ASSESSMENT.**

4 “(a) ASSESSMENT.—The Secretary shall undertake a
5 tobacco products and other nicotine delivery alternatives
6 comparative health risk assessment and rank each cat-
7 egory of products on a scale according to the reasonable
8 expectation for morbidity and mortality risk when com-
9 pared to smoking cigarettes based on laboratory studies
10 and existing scientific data. For purposes of such assess-
11 ment, tobacco and nicotine delivery alternative product
12 categories shall include at a minimum—

13 “(1) cigarettes;

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

16 “(3) little cigars;

17 “(4) cigars;

18 “(5) pipe tobacco;

19 “(6) moist snuff;

20 “(7) dry snuff;

21 “(8) chewing tobacco;

22 “(9) snus;

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

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

1 “(12) shish and other tobacco products that are
2 heated and inhaled via a hookah, water pipe, or
3 other type of pipe (treated collectively as a single
4 category);

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

8 “(14) tobacco and nicotine skin creams, patch-
9 es, and other tobacco and nicotine products intended
10 for transdermal consumption (treated collectively as
11 a single category);

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

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

17 “(b) REPORT.—Not later than 18 months after the
18 date of enactment of the Cigarette Smoking Reduction
19 and Electronic Vapor Alternatives Act of 2017, the Sec-
20 retary shall report to the Committee on Energy and Com-
21 merce of the House of Representatives and the Committee
22 on Health, Education, Labor, and Pensions of the Senate
23 on the results of the comparative health risk assessment
24 under subsection (a). Based on such results, such report
25 shall include recommendations on—

1 “(1) new or improved tobacco harm reduction
2 strategies; and
3 “(2) the possible need for additional legislative
4 authorities to implement such strategies.”.