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SENATE
S.B. No. 1538

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INTRODUCED BY SENATOR VICENTE C. SOTTO III

EXPLANATORY NOTE

Vaporized Nicotine Product Systems (VNPs) are battery-run products that heat a solution (e-juice) to generate vapor that usually consists of vegetable glycerin, propylene glycol, flavorants, and nicotine. They commonly consist of an atomizer, which heats the e-juice; a cartridge, which serves as the e-juice carrier; and a power source or battery.

As of 2015, the global VNP market size was estimated to be US\$10 billion and showing continued increase in prevalence of VNP use both globally and locally¹. Such a trend threatens public health if the VNP market remains unregulated.

These VNPs are promoted as cigarette alternatives and are designed to mimic both the form as well as the physical sensation delivered by cigarettes². Some VNPs claim in their marketing labels that they are effective smoking cessation tools as well as safer alternatives to smoking. Most of these health claims are yet to be proven by concrete scientific evidence. In fact, the World Health Organizations (WHO) has stated concerns on its safety and its sustainability as a quitting aid.

VNP use may still pose a health risk to users. The vapor generated still contains the usual toxicants that are found in cigarette smoke such as formaldehyde, volatile organic compounds, tobacco-specific nitrosamines, metals, silicate particles, polycyclic aromatic hydrocarbons, and other carcinogens – albeit at much lower levels. At high levels, these substances are known to cause respiratory and vascular diseases apart from cancer. The VNP aerosol also contains nicotine, although not a carcinogen, is still an addictive substance.

¹ Conference of the Parties to the WHO Framework Convention on Tobacco Control 7th session report

² Philippine College of Chest Physicians Position Statement on Electronic Cigarettes (E-Cigarettes)/ Electronic Nicotine Delivery Devices (ENDD)

One study also suggests that VNP use may initialize youth uptake³. The flavorings that are present in e-juices, such as chocolate and candy-like flavors, may appeal to minors and cause youth uptake. By perpetuating the behavior of smoking, VNP use have the potential to undermine smoking cessation efforts⁴.

The lack of a regulatory scheme to oversee product standards and safety has also led to the placement of inferior quality products in the Philippine market. In fact, media reports of exploding VNP products are becoming increasingly common, with more than 200 reports of VNP-related explosions⁵ all over the world. These regrettable events could have been prevented had there been a proper regulatory scheme in place.

This bill proposes that VNP products be regulated in such a way that any health claim is assessed by the Food and Drug Administration (FDA), registration and product quality and safety are in line with the standards set by the Department of Trade and Industry (DTI), sales and distribution to and from minors are prohibited, and both public and environmental health are protected.

Moreover, contained in this proposed bill is a provision on “*public place use*”, which specifies the places where VNPs may be validly used. Thus, this measure seeks to fill in the gap of Executive Order No. 26 issued by President Rodrigo Duterte on May 16, 2017 which prohibits smoking in “enclosed public spaces and public conveyances except in certain designated smoking areas” as the aforesaid executive order does not cover VNPs.

The immediate passage of this bill is earnestly requested.



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³ Department of Health Website <http://www.doh.gov.ph/node/64>

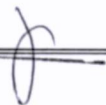
⁴ Philippine College of Chest Physicians Position Statement on Electronic Cigarettes (E-Cigarettes)/ Electronic Nicotine Delivery Devices (ENDD)

⁵ <https://www.pressreader.com/philippines/the-philippine-star/20161216/281822873440154>;
<https://theproductlawyers.com/exploding-e-cig/explosion-timeline/>; <http://ecigarette-explosionclassaction.com/tag/exploding-e-cigarettes-manila-ar-72442/>

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AN ACT
REGULATING VAPORIZED NICOTINE PRODUCTS

Be it enacted by the Senate and House of Representatives of the Philippines in Congress assembled:

1 **SECTION 1. Short Title.** – This Act shall be known as the “*Vaporized Nicotine*
2 *Products Regulation Act.*”

3 **SEC. 2. Declaration of Policy.** – It is hereby declared the policy of the State to
4 protect and promote the right to health of the people and instill health consciousness among
5 them.

6 It is further declared the policy of the State to discourage the use of cigarette products
7 and to look for effective measures in the fight against cigarette smoking by encouraging the
8 availability of well-regulated, significantly less harmful alternatives to cigarettes for smokers
9 who do not or cannot quit smoking.

10 **SEC. 3. Definitions.** As used in this Act, the following terms shall mean –

11 (a) “Vaporized nicotine product” means a product with or without tobacco that
12 generates a nicotine-containing aerosol without combustion, with or without
13 electronics or any component of that product, this includes but is not limited to a
14 cartridge, a tank and the device without a cartridge or tank.

15 (b) “Ingredient” means any substance that is added to the tobacco or nicotine mixture
16 and present in the finished product.

- 1 (c) "Nicotine" means nicotinic alkaloids, including any salt or complex of nicotine
2 whether derived from tobacco or synthetically produced.
- 3 (d) "Nicotine mixture" means the nicotine-containing liquid, solid or other non-
4 tobacco substance in the product.
- 5 (e) "Refill container" means a receptacle for holding nicotine mixture to refill certain
6 vaporized nicotine products.
- 7 (f) "Emissions" means substances that are released when a product is consumed as
8 intended, such as substances found in cigarette smoke, or the aerosol generated
9 by a vaporized nicotine products, or substances released during the process of
10 using vaporized nicotine products.
- 11 (g) "Harmful and Potentially Harmful Constituents (HPHCs)" shall refer to chemical
12 substances that pose potential health risks such as those identified by the World
13 Health Organization.
- 14 (h) "Reduced exposure claim" means a communication to consumers in the product
15 label or marketing material that the product or its emissions contain a reduced
16 level of, or are free of, a substance or substances or present a reduced exposure to
17 a substance or substances, such as HPHCs.
- 18 (i) "Reduced risk claim" means a communication to consumers in the product label
19 or marketing which represents explicitly or implicitly that the product presents a
20 lower risk or is less harmful than continued cigarette smoking.
- 21 (j) "Package" shall refer to packs, boxes, cartons or containers of any kind in which
22 the electronic component of a vaporized nicotine product is offered for sale to
23 consumers.
- 24 (k) "Nicotine receptacle" shall refer to bottles, boxes, cartons, or containers of any
25 kind in which a nicotine-containing solution or vaporized tobacco or any related

1 product is offered for sale to consumers for use with a vaporized nicotine product
2 system.

3 (l) "Point-of-sale" shall refer to any location at which an individual can purchase or
4 otherwise obtain vaporized nicotine products.

5 (m) "Principal display surface" shall refer to the panel of the nicotine receptacle that
6 faces the consumer when displayed for sale.

7 (n) "Advertising" shall refer to the business of conceptualizing, presenting, making
8 available and communicating to the public, through any form of mass media, any
9 fact, data, or information about the attributes, features, quality or availability of
10 consumer products, services, or credit. For the purpose of this Act, advertising
11 shall be understood as vaporized nicotine product advertising.

12 **SEC. 4. Packaging Content.** – The packaging shall contain the following:

13 (a) A list of all vaporized nicotine product device components; and

14 (b) A leaflet or insert containing instructions for handling, proper use, and
15 maintenance. It shall also include warnings against improper usage.

16 **SEC. 5. Health Warnings.** – Only nicotine receptacles shall bear textual health
17 warnings with the following specifications:

18 (a) Unit packets and any outside wrapping of vaporized nicotine product nicotine
19 receptacles such as e-juices, tobacco cartridges not intended for combustion, and
20 similar products, shall carry the following health warning: 'This product may
21 damage your health and is addictive'.

22 (b) The health warning shall occupy 30% of the lower part of the principal display
23 surface of the unit packet and any outside wrapping of the nicotine receptacle.
24 The health warning shall occupy a total area of not less than fifty percent (50%)
25 of the total warning frame.

1 (c) Nothing shall be printed or applied on a location where it is likely to obscure or
2 cover, in part or in whole, the health warning.

3 (d) No part of the warning may be obliterated, obscured, folded, severed or become
4 unreadable when the nicotine receptacle is opened or closed or when a wrapper
5 on the receptacle is removed.

6 Vaporized nicotine products shall not be covered by the Graphic Health Warnings
7 Law.

8 **SEC. 6. *Minimum Age Sales and Purchase.*** - The following acts shall be prohibited:

9 (a) The sale and distribution, or transfer of vaporized nicotine products by any person
10 to minors (anyone below 18 years old);

11 (b) Purchasing, or otherwise receiving vaporized nicotine products from a minor; and

12 (c) The sale, purchase, and use of vaporized nicotine products by minors.

13 It shall not be a defense for the person selling or distributing the vaporized nicotine
14 product/s that he/she did not know or was not aware of the real age of the minor. Neither
15 shall it be a defense that he/she did not know nor had any reason to believe that the product
16 was for the consumption of the minor to whom it was sold.

17 **SEC. 7. *Point-of-sale Signage.*** - Point-of-sale establishments offering, distributing,
18 or selling vaporized nicotine products to consumers shall post the following statement in a
19 clear and conspicuous manner: "SALE/DISTRIBUTION TO OR PURCHASE BY MINORS
20 OF VAPORIZED NICOTINE PRODUCTS IS UNLAWFUL" or "IT IS UNLAWFUL FOR
21 VAPORIZED NICOTINE PRODUCTS TO BE SOLD/DISTRIBUTED TO OR
22 PURCHASED BY PERSONS UNDER 18 YEARS OF AGE."

23 **SEC. 8. *Proof of Age Verification.*** - Retailers shall ascertain that no individual
24 purchasing a vaporized nicotine product is below eighteen (18) years of age. In case of

1 doubt, retailers shall verify the age of the buyer through any valid identification card
2 exhibiting the buyer's photograph and age or date of birth.

3 **SEC. 9. Advertisement Restrictions.** – Advertisements shall be allowed in points-of-
4 sale, through direct marketing, and on the internet. The following restrictions shall apply to
5 all vaporized nicotine product advertisements:

6 (a) Advertisements shall not be aimed at or particularly appeal to persons under
7 eighteen (18) years of age;

8 (b) Advertisements shall not contain cartoon characters or subjects that depict
9 humans or animals with comically exaggerated features or that attribute human or
10 unnatural characteristics to animals, plants or other objects;

11 (c) Advertisements shall only depict persons who are or who appear to be above
12 twenty-five (25) years of age;

13 (d) Advertisements shall not show, portray or depict scenes where the actual use of,
14 act of using, or puffing of vaporized nicotine products;

15 (e) Advertisements should not undermine quit-smoking messages and encourage
16 non-tobacco or nicotine users to use the product;

17 (f) Advertisements do not contain any information or element that is untrue or not
18 scientifically substantiated, in particular with regards to product characteristics,
19 health effects, risks or emissions;

20 (g) Promotional communications shall allow for adult consumers to learn about the
21 availability of vaporized nicotine products, receive information about how to use
22 them, try them before purchasing them, subject to proof of age and certification
23 of smoker status, and receive pre-sale and after-sales support;

24 (h) Advertisements shall not appear in television, radio, and cinema; and

1 (i) All allowable advertisements and promotional materials for nicotine receptacles
2 shall contain the health warning ‘This product may damage your health and is
3 addictive.’ The health warning shall occupy ten percent of the bottom area of the
4 advertisement.

5 **SEC. 10. *Restrictions on Advertisement in Print Media.*** - Advertising and other
6 promotional communications of vaporized nicotine products shall be permitted so long as the
7 publication is not intended for minors and generally has an adult readership or subscriber
8 base.

9 **SEC. 11. *Public Place Use.*** - Use of vaporized nicotine products indoor is prohibited
10 in places of worship, hospitals or other healthcare centers, public conveyances, government
11 offices, and educational or recreational facilities exclusively intended for minors. In all other
12 enclosed places that are open to the general public, private workplaces and those places not
13 covered in the preceding enumeration, vaporized nicotine product use shall be allowed,
14 provided that the owner, proprietor, operator, possessor, manager or administrator of such
15 places shall post the following statement in a clear and conspicuous manner at every ingress
16 point of the such places: “USE OF VAPORIZED NICOTINE PRODUCTS IS ALLOWED
17 INSIDE.”

18 **SEC. 12. *Product Standards and Assessment.*** – Vaporized nicotine products must
19 comply with the following:

20 (a) Vaporized nicotine products shall operate in such a way that no combustion of the
21 tobacco or nicotine mixture occurs during the entire process of consumption
22 when used as intended;

23 (b) All products must be manufactured in accordance with an appropriate quality
24 management system. The quality management system must ensure batch-to-batch
25 reproducibility of the products through quality control of both incoming materials

1 and finished products; prevention of mix-ups; and traceability from raw material
2 supplier to distributor, with supporting documented evidence and a controlled
3 change management process;

4 (c) The substances listed below may not be added in vaporized nicotine products:

- 5 i. additives that have carcinogenic, mutagenic or reprotoxic properties in
6 unburnt form;
- 7 ii. respiratory sensitizers;
- 8 iii. ethylene glycol;
- 9 iv. diethylene glycol;
- 10 v. diacetyl; and
- 11 vi. 2,3-pentanedione;

12 (d) Manufacturers of electrical devices intended to be used in combination with a
13 vaporized nicotine product shall ensure that such devices comply with applicable
14 electrical safety standards; and

15 (e) Batteries must comply with applicable industry requirements.

16 **SEC. 13. *Tamper-proof and Child-proof Designs.*** - All receptacles containing
17 nicotine mixtures must be child-resistant, tamper-resistant and protected against breakage and
18 leakage.

19 **SEC. 14. *Market Placing.*** - Manufacturers and distributors must comply with the
20 following:

21 (a) Three (3) months prior to placing a vaporized nicotine product in the market, all
22 manufacturers and importers must register their products with the Department of
23 Trade and Industry (DTI) and submit information demonstrating compliance with
24 product standards and assessment requirements;

1 (b) Manufacturers or importers intending to present the product with any information
2 about the product's health effects such as reduced exposure or reduced risk
3 claims, must submit scientific evidence supporting such consumer
4 communication to the Food and Drug Administration (FDA); and

5 (c) For products that are already in-market, they shall be given three months to
6 register their products with the DTI and submit information demonstrating
7 compliance with product standards and assessment requirements. Any health
8 claims for in-market products shall also be submitted to the FDA for approval.

9 **SEC. 15. *Health Claims.*** – Notwithstanding the foregoing provisions, there are only
10 two (2) claims that vaporized nicotine product manufacturers and distributors may make: (i) a
11 reduced exposure claim and (ii) a reduced risk claim. The FDA shall be the responsible
12 authority with respect to claims of reduced exposure or reduced risk.

13 (a) A reduced exposure claim may be made only if:

14 i. The manufacturer characterizes the levels of nicotine uptake from
15 vaporized nicotine products compared to cigarette smoking based on
16 clinical trials;

17 ii. The manufacturer can support the claim with evidence from clinical
18 trials conducted over a period of at least seven days demonstrating that,
19 compared to continued cigarette smoking, users who switch
20 completely to the product show a significant reduction in exposure to
21 one or more HPHCs based on validated, scientifically-accepted
22 biomarkers of exposure and that the reductions in exposure are
23 significant enough that a reasonable scientific or medical expert would
24 anticipate a reduction in risk of disease in smokers who switched to the
25 product;

1 iii. The manufacturer demonstrates that the average user of tobacco
2 product who is reasonably well-informed and reasonably observant and
3 circumspect correctly comprehends the claim; and

4 iv. Clinical studies must be performed in accordance with ethical
5 principles that have their origin in the Declaration of Helsinki and be
6 consistent with reasonable internationally accepted standards.

7 (b) A reduced risk claim may only be made if:

8 i. The manufacturer meets the requirements stipulated for reduced
9 exposure claims;

10 ii. The manufacturer can support the claim with clinical studies; and

11 iii. The manufacturer can support the claim with evidence from clinical
12 trials conducted over a period of at least ninety days demonstrating
13 that,

14 1. compared to continued cigarette smoking, users who switch
15 completely to the product in conditions of actual use show a
16 significant reduction in the level of each biomarker of exposure
17 to HPHCs or that the reductions are within 20% of the
18 reduction observed in smokers who quit cigarette smoking over
19 the study period, and

20 2. compared to continued cigarette smoking, users who switch
21 completely to the product in conditions of actual use show a
22 reduction in risk of harm or harm compared to continued
23 smoking.

24 Products substantiated as “reduced exposure” or “reduced risk” pursuant to this
25 Section may make such claims on product packaging and nicotine receptacles.

1 (c) To characterize risk reduction in the absence of epidemiological evidence, a
2 manufacturer may instead demonstrate favorable biological and physiological
3 changes in chosen clinical risk endpoints as compared to continued smoking.
4 These endpoints need to be effected by smoking, linked to smoking related
5 disease and reversible after smoking cessation. The majority of the assessed
6 clinical risk endpoints must shift in the direction of smoking cessation.

7 (d) A reduced exposure, or reduced risk claim is permissible only with regard to
8 products for which adequate post-marketing surveillance is in place. The
9 notification must include the plans for such post-marketing surveillance and
10 studies to determine the impact of the marketing of the product on the population.

11 **SEC. 16. Penalties for Noncompliance.** – The following penalties shall individually
12 apply to manufacturers, importers, distributors, and sellers of vaporized nicotine products as
13 well as their agents/representatives for any violation of this Act:

14 (a) On the first offense, a fine of not more than One hundred thousand pesos
15 (P100,000.00);

16 (b) On the second offense, a fine of not more than Five hundred thousand pesos
17 (P500,000.00); and

18 (c) On the third offense, a fine of not more than One million pesos
19 (P1,000,000.00) or imprisonment of not more than five (5) years, or both, at the discretion of
20 the court: Provided, That the business permits and licenses, in the case of a business entity or
21 establishment shall be revoked or cancelled.

22 Non-compliant vaporized nicotine products found in the market for sale or
23 distribution shall be subject to confiscation.

1 If the guilty officer is a foreign national, he shall be deported after service of sentence
2 and/or payment of applicable fines without need of further deportation proceedings and shall
3 be permanently barred from re-entering the Philippines.

4 **SEC. 17. *Creation of a Congressional Oversight Committee.*** – A Congressional
5 Oversight Committee co-chaired by the Senate Committees on Trade, Commerce, and
6 Entrepreneurship and Health and Demography and the House Committees on Trade and
7 Health, is hereby constituted to monitor and review the implementation of this Act.

8 **SEC. 18. *Implementing Rules and Regulations.*** – Within six (6) months from the
9 date of effectivity of this Act, the DTI, in consultation with the FDA of the Department of
10 Health, shall issue the implementing rules and regulations of this Act. The non-issuance of
11 the IRR will not suspend the effectivity of this Act or the introduction of new vaporized
12 nicotine products in the market.

13 **SEC. 19. *Separability Clause.*** – If any provision or part hereof, is held invalid or
14 unconstitutional, the remainder of the law or the provision not otherwise affected shall remain
15 valid and subsisting.

16 **SEC. 20. *Repealing Clause.*** – Any law, presidential decree or issuance, executive
17 order, letter of instruction, administrative order, rule or regulation contrary to or is
18 inconsistent with the provision of this Act is hereby repealed, modified, or amended
19 accordingly.

20 **SEC. 21. *Effectivity Clause.*** – This Act shall take effect fifteen (15) days after its
21 publication in at least two (2) newspapers of general circulation.

Approved,