

EIGHTEENTH CONGRESS OF THE }
REPUBLIC OF THE PHILIPPINES }
First Regular Session }

S E N A T E
S.B. No. 496

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INTRODUCED BY SENATOR VICENTE C. SOTTO III

**AN ACT
REGULATING VAPORIZED NICOTINE PRODUCTS**

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.

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)

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.

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

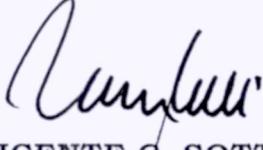
³ Department of Health Website <http://www.doh.gov.ph/node/64>

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/>

“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.



VICENTE C. SOTTO III

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2019
Senate of the Philippines
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SENATE

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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
2 Nicotine Products Regulation Act.”

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

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

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

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

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

vaporized tobacco or any related product is offered for sale to consumers for use with a vaporized nicotine product system.

- (l) "Point-of-sale" shall refer to any location at which an individual can purchase or otherwise obtain vaporized nicotine products.
- (m) "Principal display surface" shall refer to the panel of the nicotine receptacle that faces the consumer when displayed for sale.
- (n) "Advertising" shall refer to the business of conceptualizing, presenting, making available and communicating to the public, through any form of mass media, any fact, data, or information about the attributes, features, quality or availability of consumer products, services, or credit. For the purpose of this Act, advertising shall be understood as vaporized nicotine product advertising.

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

- (a) A list of all vaporized nicotine product device components; and
- (b) A leaflet or insert containing instructions for handling, proper use, and maintenance. It shall also include warnings against improper usage.

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

- (a) Unit packets and any outside wrapping of vaporized nicotine product nicotine receptacles such as e-juices, tobacco cartridges not intended for combustion, and similar products, shall carry the following health warning: 'This product may damage your health and is addictive'.
- (b) The health warning shall occupy 30% of the lower part of the principal display surface of the unit packet and any outside wrapping of the nicotine receptacle. The health warning shall occupy a total area of not less than fifty percent (50%) of the total warning frame.
- (c) Nothing shall be printed or applied on a location where it is likely to obscure or cover, in part or in whole, the health warning.

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

4 Vaporized nicotine products shall not be covered by the Graphic
5 Health Warnings Law.

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

- 8 (a) The sale and distribution, or transfer of vaporized nicotine
9 products by any person to minors (anyone below 18 years old);
10 (b) Purchasing, or otherwise receiving vaporized nicotine products
11 from a minor; and
12 (c) The sale, purchase, and use of vaporized nicotine products by
13 minors.

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

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

26 **SEC. 8. Proof of Age Verification.** - Retailers shall ascertain that no
27 individual purchasing a vaporized nicotine product is below eighteen (18)
28 years of age. In case of doubt, retailers shall verify the age of the buyer
29 through any valid identification card exhibiting the buyer's photograph and
30 age or date of birth.

31 **SEC. 9. Advertisement Restrictions.** - Advertisements shall be
32 allowed in points-of-sale, through direct marketing, and on the internet. The

1 following restrictions shall apply to all vaporized nicotine product
2 advertisements:

- 3 (a) Advertisements shall not be aimed at or particularly appeal to
4 persons under eighteen (18) years of age;
- 5 (b) Advertisements shall not contain cartoon characters or subjects
6 that depict humans or animals with comically exaggerated
7 features or that attribute human or unnatural characteristics to
8 animals, plants or other objects;
- 9 (c) Advertisements shall only depict persons who are or who appear to
10 be above twenty-five (25) years of age;
- 11 (d) Advertisements shall not show, portray or depict scenes where the
12 actual use of, act of using, or puffing of vaporized nicotine
13 products;
- 14 (e) Advertisements should not undermine quit-smoking messages and
15 encourage non-tobacco or nicotine users to use the product;
- 16 (f) Advertisements do not contain any information or element that is
17 untrue or not scientifically substantiated, in particular with
18 regards to product characteristics, health effects, risks or
19 emissions;
- 20 (g) Promotional communications shall allow for adult consumers to
21 learn about the availability of vaporized nicotine products, receive
22 information about how to use them, try them before purchasing
23 them, subject to proof of age and certification of smoker status,
24 and receive pre-sale and after-sales support;
- 25 (h) Advertisements shall not appear in television, radio, and cinema;
26 and
- 27 (i) All allowable advertisements and promotional materials for
28 nicotine receptacles shall contain the health warning 'This product
29 may damage your health and is addictive.' The health warning
30 shall occupy ten percent of the bottom area of the advertisement.

31 **SEC. 10. *Restrictions on Advertisement in Print Media.*** -

32 Advertising and other promotional communications of vaporized nicotine

1 products shall be permitted so long as the publication is not intended for
2 minors and generally has an adult readership or subscriber base.

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

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

- 16 (a) Vaporized nicotine products shall operate in such a way that no
17 combustion of the tobacco or nicotine mixture occurs during the
18 entire process of consumption when used as intended;
- 19 (b) All products must be manufactured in accordance with an
20 appropriate quality management system. The quality management
21 system must ensure batch-to-batch reproducibility of the products
22 through quality control of both incoming materials and finished
23 products; prevention of mix-ups; and traceability from raw
24 material supplier to distributor, with supporting documented
25 evidence and a controlled change management process;
- 26 (c) The substances listed below may not be added in vaporized
27 nicotine products:
 - 28 i. additives that have carcinogenic, mutagenic or reprotoxic
29 properties in unburnt form;
 - 30 ii. respiratory sensitizers;
 - 31 iii. ethylene glycol;
 - 32 iv. diethylene glycol;
 - 33 v. diacetyl; and

1 vi. 2,3-pentanedione;

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

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

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

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

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

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

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

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

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

- i. The manufacturer characterizes the levels of nicotine uptake from vaporized nicotine products compared to cigarette smoking based on clinical trials;
- ii. The manufacturer can support the claim with evidence from clinical trials conducted over a period of at least seven days demonstrating that, compared to continued cigarette smoking, users who switch completely to the product show a significant reduction in exposure to one or more HPHCs based on validated, scientifically-accepted biomarkers of exposure and that the reductions in exposure are significant enough that a reasonable scientific or medical expert would anticipate a reduction in risk of disease in smokers who switched to the product;
- iii. The manufacturer demonstrates that the average user of tobacco product who is reasonably well-informed and reasonably observant and circumspect correctly comprehends the claim; and
- iv. Clinical studies must be performed in accordance with ethical principles that have their origin in the Declaration of Helsinki and be consistent with reasonable internationally accepted standards.

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

- i. The manufacturer meets the requirements stipulated for reduced exposure claims;
- ii. The manufacturer can support the claim with clinical studies; and
- iii. The manufacturer can support the claim with evidence from clinical trials conducted over a period of at least ninety days demonstrating that,
 1. compared to continued cigarette smoking, users who switch completely to the product in conditions of actual use show a significant reduction in the level of each biomarker of exposure to HPHCs or

that the reductions are within 20% of the reduction observed in smokers who quit cigarette smoking over the study period, and

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

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

- (c) To characterize risk reduction in the absence of epidemiological evidence, a manufacturer may instead demonstrate favorable biological and physiological changes in chosen clinical risk endpoints as compared to continued smoking. These endpoints need to be effected by smoking, linked to smoking related disease and reversible after smoking cessation. The majority of the assessed clinical risk endpoints must shift in the direction of smoking cessation.
 - (d) A reduced exposure, or reduced risk claim is permissible only with regard to products for which adequate post-marketing surveillance is in place. The notification must include the plans for such post-marketing surveillance and studies to determine the impact of the marketing of the product on the population.

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

- 28 (a) On the first offense, a fine of not more than One hundred
29 thousand pesos (P100,000.00);
30 (b) On the second offense, a fine of not more than Five hundred
31 thousand pesos (P500,000.00); and
32 (c) On the third offense, a fine of not more than One million pesos
33 (P1,000,000.00) or imprisonment of not more than five (5) years, or both, at

1 the discretion of the court: Provided, That the business permits and
2 licenses, in the case of a business entity or establishment shall be revoked
3 or cancelled.

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

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

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

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

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

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

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

Approved,