Republic of the Philippines
HOUSE OF THE REPRESENTATIVES
Quezon City

EIGHTEENTH CONGRESS
First Regular Session

HOUSE BILL No. 1508

Introduced by REPRESENTATIVES ALFREDO A. GARBIN, Jr. and ELIZALDY S. CO

EXPLANATORY NOTE

A wide range of vaporized nicotine products have been introduced in the Philippines and globally.[1] They are handheld devices which may be battery operated that deliver nicotine by vaporizing a nicotine-containing liquid[2] or by heating, instead of burning, tobacco. Vaporized nicotine products are generally made up of three basic parts, an atomizer, a cartridge, and a rechargeable battery. The cartridge stores the solution (e-juice) that is commonly composed of propylene glycol, glycerol, nicotine, and flavorings. The e-juice is heated and turned into vapor by the heating element, the atomizer. Other products heat tobacco instead of burning it.[3] Designed to mimic the smoking experience without burning tobacco, many in the public health community have expressed the view that they are less hazardous alternatives to cigarettes.[4] At the same time, many have expressed concerns about the safety and quality of such products.

With the introduction into the market of e-cigarettes in 2007, vaporized nicotine products (*i.e.*, electronic cigarettes or novel non-combustible tobacco products) are now becoming an increasingly popular choice among smokers, either on the assumption that such products pose less risk to conventional smoking-related diseases, or that such products are vehicles to quitting smoking altogether. There are also many custom vaporized nicotine products manufactured in the Philippines. However, regulation on the packaging, use, sale and distribution, and advertising of these products is wanting. This poses possible dangers to adult consumers, who should be assured by manufacturers of the quality and safety of such products and informed of the components found in the

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[1] http://onlinelibrary.wiley.com/doi/10.1111/add.13394/abstract; https://gumc.georgetown.edu/news/Top-Tobacco-Control-Experts-To-FDA-Studies-of-E-cigs-Suggest-More-Benefit-Than-Harm
[2] http://www.ash.org.uk/files/documents/ASH_715.pdf
[3] http://onlinelibrary.wiley.com/doi/10.1111/add.13394/abstract
[4] http://nicotinepolicy.net/documents/letters/MargaretChan.pdf

same. There have been reported incidents of exploding batteries or defective electrical systems which need to be addressed.

Moreover, adult consumers should not be made to believe that such products indeed have the propensity for harm reduction due to smoking, and manufacturers and distributors should not be allowed to freely claim nor indirectly imply that such products are safer alternatives, in the absence of any definitive finding and approval by the Philippine Food and Drug Administration (FDA) that vaporized nicotine products can be regarded as reduced risk nicotine-delivery systems.

Vaporized nicotine products should be differentiated in terms of regulation from conventional cigarettes as studies have consistently concluded that vaporized nicotine products are significantly safer than conventional tobacco smoking.[5] This is largely attributable to the fact that conventional cigarettes release much more carcinogens and toxins from the combustion process that burns tobacco, whereas vaporized nicotine products forego the combustion process completely. As a less harmful form of nicotine delivery, the 2016 report of the Royal College of Physicians (RCP) of the United Kingdom suggested that e-cigarettes, a kind of vaporized nicotine product, can be an effective tool in harm-reduction as well as a gateway to smoking reduction and cessation.[6]

Currently, e-cigarettes are regulated as "health-related devices", requiring a medicines license from the Food and Drug Administration (FDA).[7] This type of regulation, however, is too rigid and may restrict further developments due to the licensing applications required per improvement or change done on the device.[8] Medicines require evidence of safety; efficacy at treating or preventing a disease in a defined dose based on clinical studies; and manufacturing in pharmaceutical facilities. All these will increase the cost of e-cigarettes and other types of vaporized nicotine products, which would make conventional tobacco cigarettes more appealing. At the end of the day, this kind of regulatory regime will kill the fledgling e-cigarette industry, negate the prospect of harm reduction for the smoking public, and discourage smokers from switching to safer alternatives to cigarettes. It would also be impractical to regulate vaporized nicotine products as basic consumer products as this does not have enough

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[5] http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4110871/pdf/10.1177_2042098614524430.pdf ; http://journals.plos.org/plosone/article?id=10.1371/journal.pone.0122544 ; https://www.heartland.org/sites/default/files/tob_control-2016-manzoli-tobaccocontrol-2015-052822_0.pdf ;

[6] https://www.rcplondon.ac.uk/projects/outputs/nicotine-without-smoke-tobacco-harm-reduction-0

[7] DOH Administrative Order 2014-0008

[8] http://www.clivebates.com/?p=1252

protection regulations for their potentially toxic components and lack restriction on youth access.

There are also proposals to regulate vaporized nicotine products as tobacco products due to their nicotine content, a tobacco derivative. Regulating them in the exact same way as cigarettes, however, would carry a misleading message that they are as harmful as tobacco cigarettes. Groups such as Public Health England and the British Lung Foundation have underscored the importance of regulating vaporized nicotine products differently from cigarettes.[9]

This bill will require manufacturers to register their vaporized nicotine products with the Department of Trade and Industry prior to market placement to ensure that such products have sufficiently passed quality and safety requirements and avoid untoward incidents to consumers during use. The following health warning is likewise mandated on nicotine receptacles of vaporized nicotine products: 'This product may damage your health and is addictive,' in line with their risk profile which is different from that of conventional cigarettes. Health claims, such as reduced exposure to disease and reduced risk, can only be made subject to the approval of the FDA and based on scientifically validated tests. This will prevent the assertion of misleading claims to the public.

The medical community[10] acknowledges that a wide range of novel products is emerging that eliminates combustion and, as such, can be an integral part of harm reduction. Also, the current proliferation and availability of such unregulated novel products in the market today warrants the exigent development of a unique regulatory scheme without the rigidity of medicine licensing, separate from conventional tobacco regulation, but stricter than consumer product regulation. This bill proposes the creation of a new product category and the formation of a new type of regulation for vaporized nicotine products.

In view of the foregoing, the immediate passage of this bill is earnestly requested.

ALFREDO A. GARBIN, JR.

ELIZALDY S. CO

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[9] https://www.gov.uk/government/news/vaping-in-public-places-advice-for-employers-and-organisations
[10] http://www.clivebates.com/?p=2185

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Introduced by REPRESENTATIVES ALFREDO A. GARBIN, Jr. and ELIZALDY S. CO

AN ACT
REGULATING THE USE, SALE, PACKAGING, DISTRIBUTION, AND ADVERTISEMENTS OF VAPORIZED NICOTINE PRODUCTS

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

SECTION 1. *Short Title.* – This Act shall be known as the "Vaporized Nicotine Product Regulation Act of 2016."

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

It is further declared the policy of the State to promote harm reduction measures particularly in the fight against cigarette smoking by encouraging the availability of well-regulated, significantly less harmful alternatives to cigarettes for smokers who do not or cannot quit smoking.

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

(a) "Vaporized nicotine product" means a product with or without tobacco that generates a nicotine-containing aerosol without combustion, with or without electronics or any component of that product, this includes but is not limited to a cartridge, a tank and 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 non-combustible 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

(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.

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

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

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

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

(b) Purchasing, or otherwise receiving vaporized nicotine products from a minor.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(b) All products must be manufactured in accordance with an appropriate quality management system. The quality management system must ensure batch-to-batch reproducibility of the products through quality control of both incoming materials and finished products; prevention of mix-ups; and

traceability from raw material supplier to distributor, with supporting documented evidence and a controlled change management process.

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

i. additives that have carcinogenic, mutagenic or reprotoxic properties in unburnt form; and

ii. respiratory sensitizers.

iii. ethylene glycol

iv. diethylene glycol

v. diacetyl

vi. 2,3-pentanedione

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

(e) Batteries must comply with applicable industry requirements.

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

SEC. 14. ***Market Placing.*** – Manufacturers and distributors must comply with the following:

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

(b) Manufacturers or importers intending to present the product with any information about the product's health effects such as reduced exposure or

reduced risk claims, must submit scientific evidence supporting such consumer communication to the Food and Drug Administration (FDA).

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

SEC. 15. ***Health Claims.*** – There are two claims that vaporized nicotine products may make: a reduced exposure claim and a reduced risk claim. The FDA shall be the responsible authority with respect to claims of reduced exposure or reduced risk.

(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.

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; and

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

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:

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

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

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

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

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

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

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

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

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

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

Approved,