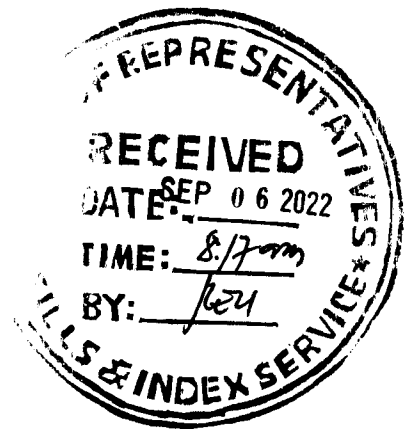


Republic of the Philippines
House of Representatives
Quezon City, Metro Manila

NINETEENTH CONGRESS
First Regular Session

House Bill No. **4449**



INTRODUCED BY REP. ANNA YORK P. BONDOC, MD

AN ACT
REGULATING THE MANUFACTURE, IMPORTATION, SALE, DISTRIBUTION, USE,
ADVERTISEMENT, PROMOTION, AND SPONSORSHIP OF ELECTRONIC
NICOTINE DELIVERY SYSTEMS AND ELECTRONIC NON-NICOTINE DELIVERY
SYSTEMS (ENDS/ENNDS), HEATED TOBACCO PRODUCTS (HTPs), AND OTHER
IMITATION TOBACCO PRODUCTS

EXPLANATORY NOTE

Republic Act No. 11467, or the *Sin Tax Reform Act of 2020*, provided stringent regulation on the manufacture, importation, sale, packaging, advertising, and distribution of vapor product and heated tobacco products (HTPs), in order to protect public health. However, even before the full implementation of the Sin Tax Law on 25 May 2022, both Houses of the 18th Congress passed the “Vaporized Nicotine and Non-Nicotine Products regulation Act” (Vape Bill) on 26 January 2022. It was transmitted by the House of Representatives with barely three (3) working days left before the end of President Rodrigo Roa Duterte’s term in office.

The Vape Bill overturns, among others, three (3) key safeguard provisions of the Sin Tax Reform Act, which the undersigned sponsored in the 18th Congress. The Vape Bill would therefore be detrimental to the health and welfare of Filipinos, especially the youth.

First, the jurisdiction to regulate vapes and HTPs will be transferred from the Food and Drug Administration (FDA) to the Department of Trade and Industry (DTI). The Regulation with the FDA as these products are harmful to health agency. The DOH and the FDA are at the forefront of tobacco control in the Philippines. The DTI does not have the mandate and the expertise to determine the health effects of any product, let alone these sin products, which are harmful to health.

Recently, the Supreme Court Decision upheld the constitutionality of the Implementing Rules and Regulations of Republic Act No. 9711, or the Food and Drug Administration Act of 2009, and ruled that the FDA has the power to regulate the health aspect of tobacco products, as these are “health product” due to their harmful effect on health. Vapes and HTPs also contain toxic substances, such as nicotine, that endanger the health of its users. As such, vapes and HTPs are also undoubtedly health products and should be maintained under the jurisdiction of the FDA.

Second, the prohibition to sell to persons below the age of 21 will be lowered to 18 years old. This means that even senior high school students will have access to vapes and HTPs. Based on the latest available data from the Department of Education (DepEd), There are 1,184,663 learners in senior high and 238,935 learners in junior high, who are at least 18, years old as of SY 2022-2021. By lowering the minimum age of access to vapes from 21 to 18, as mandated by the Vape Bill, the government would practically send the message to around 1.4 million junior and senior high school students that it’s alright to get hooked on vaping

Studies have shown that the brain continues to mature until the age of 25 and that early exposure to nicotine, through vapes and HTPs, could impair the brain’s development. This only shows that the Vape Bill is targeting the youth to buy and use vapes and HTPs

Third, the Vape Bill allows more flavors, instead of just plain tobacco and plain menthol, which will make these sin products more appealing to the youth. This will worsen the uptake in the consumption of vapes and HTPS among the youth in the country. In the Philippines, one (1) out of five (5) e-cigarettes users is aged ten (10) to nineteen (19) years old. Around eleven percent (11%) of young people aged eleven (11) to thirteen (13) have already tried e-cigarettes and there are around 550,000 adult users of e-cigarettes. This is an attempt to capitalize on the potential addiction of the youth by enticing them with more flavors contained in vapes and HTPS.

The vape Bill that is masquerading as a health bill will not only overturn important provisions under the Sin Tax Law, but it will also open the doors for younger people to use these products, and practically encourage such practice in the guise of regulation

This measure as was originally proposed in the 18th Congress in collaboration with the Southeast Asia Tobacco Control Alliance (SEATCA) and other health advocates, in order to safeguard and continue the implementation of the abovementioned important provisions in the Sin Tax Law. This bill maintains the jurisdiction of the FDA over vapes, HTPs, and other imitation tobacco products by requiring manufacturers, distributors, importers, and sellers of these said products to register with the health agency prior to market placement. The advertisement, promotion, and sponsorship of vapes, HTPs, and other imitation tobacco products shall likewise

G.R. No. 200431 (DOH and FDA v. Phil Tobacco Institute).
Centers for Disease Control and Prevention. (n.d.) *Quick Facts on the Risk of E-cigarettes for Kids, Teens and Young Adults*. https://cdc.gov/tobacco/basic_information/e-cigarettes/Quick-Facts-on-the-Risk-of-E-cigarettes-for-Kids-Teens-and-Young-Adults.html#two

be subjected to stringent regulations considering that these products pose important health risks. By regulating these products, the State is fulfilling its mandate to protect the health of our people, most especially the youth, at a time when we are experiencing and still being threatened by the ill effects of COVID-19.

Further, this bill will actually protect vape and HTP users because with the FDA's regulation, they will have more assurance that these products have undergone appropriate tests based on scientific evidence and established health standards, to ensure their quality and identify their corresponding health effects.

In view of the foregoing, the immediate approval of the bill is earnestly sought.


REP. ANNA YORK P. BONDOC, MD
4TH District Pampanga

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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 “*Vapes and HTPs Regulation Act.*”

Sec. 2. *Declaration of Policy.* – It is hereby declared the policy of the State to promote and protect the right to health of the people and instill health consciousness among them. Towards this end, the State shall implement measures to promote the general welfare by protecting the public against hazards to health and safety of Electronic Nicotine Delivery Systems and Electronic Non-Nicotine Delivery Systems (ENDS/ENNDS), Heated Tobacco Products (HTPs), and other imitation tobacco products.

Sec. 3. *Definition of Terms.* – As used in this Act, the following terms shall mean:

- (a) *Advertisement* refers to any visual and/or audible message or post generated, sent, received, or disseminated to the public about or on a particular product that promote or give publicity by words, designs, images or any other means through broadcasts, electronic, optical, print or whatever form of mass or social media, including indoor and outdoor advertisements, such as but not limited to signs and billboards.
- (b) *Advertising* refers to the business of conceptualizing, presenting, making available, and communicating to the public, through any forms of mass or social media, including documentaries and testimonials, 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 Electronic Nicotine Delivery Systems and Electronic Non-Nicotine Delivery Systems (ENDS/ENNDS), Heated Tobacco Products (HTPs) and other imitation tobacco products advertising. This shall specifically refer to any posts, messages, or images

depicting smoking or vaping as a lifestyle, or promoting or encouraging smoking or vaping, or the purchase or use of ENDS/ENNDS, HTPs, and other imitation tobacco products trademarks, brand names, design, and manufacturer's names.

- (c) *Distributor* refers to any person, entity, or establishment that imports ENDS/ENNDS, HTPs, and other imitation tobacco products for distribution to other establishments or outlets.
- (d) *Designated Vaping Area (DVA)* refers to an area of a building or conveyance where vaping may be allowed, which may be in an open space or separate area with proper ventilation subject to the specific standards provided in this Act.
- (e) *Electronic Nicotine Delivery Systems and Electronic Non-Nicotine Delivery Systems (ENDS/ENNDS)*, otherwise known as Vapes, refer to combinations of non-tobacco e-liquids, solutions or refills, and an electronic delivery device, or any combination thereof, that produce an aerosol, mist, or vapor that users inhale by mimicking the act of smoking.
- (f) *Heated Tobacco Products (HTPs)* refer to a form of tobacco product that uses an electronic device to heat processed tobacco leaves, and produces aerosols for inhalation by mimicking the behavior of smoking conventional cigarettes.
- (g) *Imitation Tobacco Products* refer to any product, device, or article –
 - (i) That resembles, or is designated to resemble or replace a tobacco product;
or
 - (ii) That is capable of being smoked or inhaled; or
 - (iii) That creates the resemblance of smoking; or
 - (iv) That may be used in such a way as to mimic the act of smoking; or
 - (v) That which is sold in a package designed to resemble the packaging commonly associated with tobacco products.

Provided, That this provision shall not apply to pharmaceutical products approved by the Food and Drug Administration (FDA) as a smoking cessation tool or device.

- (h) *Nicotine Shot/Concentrates* refer to high strength preparations of nicotine designed to be added to e-liquid preparations to increase its nicotine content.
- (i) *Promotion* refers to a social media post or an event or activity organized by, on behalf of, or together with a tobacco or imitation tobacco product manufacturer, distributor, importer or retailer with the aim of promoting a brand of ENDS/ENNDS, HTPs or other imitation tobacco products. It may also refer to the display of the product or manufacturer's name, trademark, logo, etc. This includes the paid use of ENDS/ENNDS, HTPs or imitation tobacco products bearing the brand names, trademarks, logos, etc. in social media, movies, television, and other forms of entertainment.

- (j) *Retailer* refers to any person, entity, or establishment that sells ENDS/ENNDS, HTPs, and other imitation tobacco products to individuals for personal consumption.
- (k) *Smoke/Vape-free* refers to air that is 100% free from smoke, vapor or aerosol from tobacco products, ENDS/ENNDS, HTPs, and other imitation tobacco products.
- (l) *Sponsorship* refers to any public or private contribution from a third party in relation to an event, team, or activity, or social media post which promotes a brand of ENDS/ENNDS, HTPs or other imitation tobacco products.
- (m) *Vaping* refers to the act of inhaling and exhaling the aerosol and other emissions produced by ENDS/ENNDS or other imitation tobacco products.
- (n) *Young Person* refers to any person below twenty-one (21) years old.

Sec. 4. Prohibition on the Use of ENDS/ENNDS, HTPs, and other imitation tobacco products in Public Places. – Vaping, or the use of ENDS/ENNDS, HTPs, or other imitation tobacco products shall be prohibited in all places where tobacco smoking or the use of cigarettes is prohibited by other pertinent laws and issuances. Nothing shall prevent Local Government Units (LGUs) or other government agencies from issuing ordinances or circulars providing for stricter standards or an outright ban.

Sec. 5. Prohibited Areas for Use of ENDS/ENNDS, HTPs, and other imitation tobacco products. - There shall be no designated area for the use of ENDS/ENNDS, HTPs, and other imitation tobacco products in the following public places:

- (a) Centers of youth activity such as playschools, preparatory schools, elementary schools, high schools, colleges and universities, boarding houses, dormitories, youth hostels, and recreational facilities for young and elderly persons;
- (b) Within the buildings and premises of public and private hospitals, medical, dental and optical clinics, health centers, nursing homes, dispensaries and laboratories;
- (c) Elevators and stairwells;
- (d) Locations in which fire hazards are present, including gas stations and storage areas for flammable liquids, gas, explosives or combustible material;
- (e) Food preparation and serving areas; and
- (f) Places of worship.

Sec. 6. Standards for Designated Vaping Areas – All DVAs shall strictly comply with the following standards:

- (a) The DVA shall be in an open space in an outdoor area, or in a separate indoor area with proper ventilation;
- (b) If the DVA is located indoors, there shall be no opening that will allow air to escape from the DVA to the smoke/vape-free area of the building or conveyance, except for a single door equipped with an automatic door closer *Provided*, That the buffer zone shall have no other opening except for a single door equipped with an automatic door closer, which shall

be at least two (2) meters away from the door of the DVA, and that vaping is prohibited in the buffer zone;

- (c) The DVA and its ventilation outlets shall not be located in or within ten (10) meters from entrances, exits or any place where people pass or congregate, or in front of air intake ducts;
- (d) The combined area of the DVA and the buffer zone shall not be larger than fifteen percent (15%) of the total floor area of the building or conveyance; *Provided*, That in no case shall such area be less than ten (10) square meter;
- (e) No building or conveyance shall have more than one (1) DVA;
- (f) The ventilation system for the DVA, other than in open space and for the buffer zone, shall be independent of all ventilation systems for the rest of the building or conveyance;
- (g) Young persons and pregnant women and such other vulnerable persons identified by the Department of Health (DOH) shall not be allowed inside the DVA and the buffer zone;
- (h) There shall be no selling, serving, or giving of food and beverages in the DVA and its buffer zone;
- (i) The DVA shall have no tables and chairs; and
- (j) The DVA shall have the following signages highly legible, visible and prominently displayed:
 - (i) “Vaping Area” signage;
 - (ii) Graphic health warnings (GHW) on the effects of vaping;
 - (iii) Prohibition on the entry of young persons and pregnant women and such other vulnerable persons identified by DOH; and
 - (iv) Signage stating “food and drinks are prohibited in this area”.

Provided, That nothing in this Act shall compel persons-in-charge to establish designated vaping areas nor prevent them from instituting more stringent measures in their buildings and establishments to better ensure a vape-free environment in their premises.

Sec. 7. Prohibition on Sales to and by Young Persons and Use by Young Persons – The following acts shall be prohibited:

- (a) For any retailer to sell or distribute ENDS/ENNDS, HTPs, and other imitation tobacco products to any young person;
- (b) For any person to purchase ENDS/ENNDS, HTPs, and other imitation tobacco products from a young person; and
- (c) For a young person to purchase or use ENDS/ENNDS, HTPs, and other imitation tobacco products.

For purposes of this Act, it shall not be a defense for the person selling or distributing that he or she did not know or was not aware of the real age of the young person to whom it was sold. Neither shall it be a defense that he or she did not know nor had any reason to believe that the ENDS/ENNDS, HTPs, or other imitation tobacco products was for the consumption of a young person to whom it was sold.

Sec. 8. Restrictions on Flavors. – The manufacture, sale, distribution, and use of ENDS/ENNDS, HTPs, and other imitation products with flavors other than plain tobacco or plain menthol is prohibited. No combination of other flavors shall be allowed.

Sec. 9. Prohibition on the Retail or Use of Nicotine Shots. – The retail or use of nicotine shots and/or concentrates shall be strictly prohibited.

Sec. 10. Prohibition on Online Selling of ENDS/ENNDS, HTPs, and Other Imitation Tobacco Products and Accessories. - The sale of ENDS/ENNDS, HTPs, and other imitation tobacco products and accessories via the internet, or through online markets shall be strictly prohibited.

Sec. 11. Point-of-Sale Restriction. - The distribution, sale, and offering for sale and use of ENDS/ENNDS, HTPs, and other imitation tobacco products and accessories shall be strictly prohibited in places where sale and use of conventional cigarettes shall be prohibited.

Sec. 12. Sale of ENDS/ENNDS, HTPs and Other Imitation Tobacco Products and Accessories within School Perimeters and Residential Areas. – The sale or distribution of ENDS/ENNDS, HTPs, and other imitation tobacco products and accessories is prohibited within a minimum distance of two hundred (200) meters from any point of the perimeter of a school, public playground, or other facility frequented by young persons and residential areas. Nothing in this provision or elsewhere in this Act shall be construed as limiting the powers of LGUs under the general welfare clause.

Sec. 13. License to Operate and Certificate of Product Registration. – All persons, entities, or establishments engaged in the manufacture, importation, distribution, and sale of ENDS/ENNDS, HTPs, and other imitation tobacco products shall first secure a License to Operate (LTO) from the FDA. ENDS/ENNDS, HTPs, and other imitation tobacco products shall be submitted for product registration with the FDA and shall be issued a Certificate of Product Registration (CPR) before being sold to the general public.

Sec. 14. Health Claims. – Unless approved by the FDA, any person, entity, organization, or establishment is prohibited from stating or publishing any health claims on ENDS/ENNDS, HTPs, and other imitation tobacco products, such as but not limited to claims of reduced health risk or reduced exposure to carcinogenic ingredients.

Sec. 15. Restrictions on Advertisement, Sponsorship, and Promotion – Any form of advertising, sponsorship, promotion, and promotional sales which offer price cuts, discounts, coupons, raffle prizes, exchange gifts, and bundling discounts for purchases of ENDS/ENNDS, HTPs, and other imitation tobacco products and accessories, such as but not limited to clips, bags, holders, lanyards, and other similar accessories shall be prohibited.

No person shall use the FDA logo, the words “Food and Drug Administration” or “Philippine FDA”, or any imitation of such words, initials, or logo in print and other forms of broadcast, media, including the internet, in connection with any ENDS/ENNDS, HTPs, and other imitation tobacco products and accessories, merchandise, impersonation, solicitation, or

commercial activity in a manner that convey such use is approved, endorsed, or authorized by the FDA.

Engaging in any form of ENDS/ENNDS, HTPs, and other imitation tobacco products and accessories advertisement and promotion, including advertising in social media, online media, and the internet is likewise prohibited.

Promoting, directly or indirectly, ENDS/ENNDS, HTPs, and other imitation tobacco products and accessories in an event, activity, program, or project where ENDS/ENNDS, HTPs, and imitation tobacco products and accessories company is a participant as a facilitator, sponsor, contributor, donor, or benefactor is prohibited.

Unless approved by the FDA as a cessation device, promoting or advertising, directly or indirectly, ENDS/ENNDS, HTPs, and other imitation tobacco products, as a healthier alternative to smoking or a smoking cessation tool, is prohibited.

ENDS/ENNDS, HTPs, and other imitation tobacco products and accessories importers, manufacturers, sellers, distributors, and retailers are prohibited from directly or indirectly sponsoring any sport, concert, educational, cultural, art, or any event.

Individual or team athletes, artists, performers, influencers, and health professionals are likewise prohibited from accepting sponsorships, endorsing, posting, or promoting ENDS/ENNDS, HTPs, and other imitation products and accessories, which includes the mention or tagging through social media, of the names or brands of ENDS/ENNDS, HTPs, and other imitation tobacco products and accessories. All persons receiving remuneration, in whatever form, for promoting or encouraging the use of ENDS/ENNDS, HTPs, and other imitation tobacco products shall also be covered by the ban under this Section.

Sec 16. Smoking/Vaping Restriction Awareness Campaign. - The DOH, as may be necessary, shall prescribe guidelines for the implementation of smoking/vaping restriction awareness campaigns, which may include but not be limited to information drives, and posting of warning signages in public.

Sec. 17. Warning on Packaging of ENDS/ENNDS, HTPs, and Other Imitation Tobacco Products. – All containers and packages of ENDS/ENNDS and HTPs shall bear the graphic health warnings as provided under Republic Act No. 10643 or the “Graphic Health Warnings Law.” All containers and packages of other imitation tobacco products or its accessories shall contain appropriate health warnings, whose content, format, and specifications are to be designated by the DOH: *Provided*, That the DOH shall regularly review and revise the said health warnings, and issue additional warnings and messages on health risks as they deem appropriate.

Sec. 18. Role of Government Agencies. – The DOH, in consultation with the FDA, the Department of Trade and Industry (DTI), and concerned agencies, shall promulgate rules, regulations, and standards on packaging, ingredients, graphic health warning, detailed information on the allowable nicotine containing e-liquid, the strength of e-liquids, compliance with applicable electrical and safety standards.

The FDA, in collaboration with LGUs, shall check the compliance of manufacturers, importers, distributors, and retailers with this Act through surveillance inspections and investigations and take appropriate action for non-compliance.

The DepEd and CHED, in coordination with the DOH, shall conduct an information campaign on nicotine addiction and the ill effects of smoking and vaping.

LGUs are encouraged to enact local ordinances in support of the minimum mandatory requirements under this Act and the general welfare of their constituents. Nothing in this Act shall be construed as limiting the powers of LGUs under the general welfare clause: *Provided*, That the minimum requirements under this Act are complied with.

Sec. 19. Penalties. – The following penalties shall apply:

- (a) Violations of Sections 4 and 5 of this Act:
 - (i) First offense: a fine of not less than Five Thousand Pesos (PhP 5,000.00) but not more than Ten Thousand Pesos (PhP10,000.00) shall be imposed.
 - (ii) Second Offense: a fine of not less than Ten Thousand Pesos (PhP10,000.00) but not more than Twenty Thousand Pesos (PhP20,000.00) shall be imposed.
 - (iii) Third Offense: In addition to a fine of Twenty Thousand Pesos (PhP20,000.00), the business permits and licenses to operate shall be cancelled or revoked.
- (b) Violation of Section 7 of this Act:
 - (i) First offense: a fine not less than Twenty Thousand Pesos (PhP 20,000) or an imprisonment of not more than thirty (30) days, upon the discretion of the court. For succeeding offenses, both penalties shall apply in addition to the revocation of business licenses or permits in the case of a business entity or establishment.
 - (ii) The DOH and the Department of Social Welfare and Development (DSWD) shall implement appropriate intervention programs, including but not limited to, counselling of young person and his/her parent/guardian, when a young person is caught selling, buying, or using ENDS/ENNDS, HTPs, and other imitation tobacco products.
- (c) Violations of Sections 8 to 15 of this Act:
 - (i) First offense: a fine of not more than One Hundred Thousand Pesos (PhP 100,000.00) or imprisonment of not more than one (1) year, or both, at the discretion of the court shall be imposed.
 - (ii) Second Offense: a fine of not more than Two Hundred Thousand Pesos (PhP 200,000.00) or imprisonment of not more than two (2) years, or both, at the discretion of the court shall be imposed.

- (iii) Third Offense: in addition to a fine of not more than Four Hundred Thousand Pesos (PhP 400,000.00) or imprisonment of not more than three (3) years, or both, at the discretion of the court, and in the case of a business entity, partnership, corporation, association, or any juridical person, the business permits, licenses, in the case of a business entity or establishment, shall be revoked or cancelled.
- (d) Violation of Section 17 of this Act shall be penalized in accordance to Section 14 of Republic Act No. 10643 otherwise known as “the Graphic Health Warnings Law.

In case any violation of this Act is committed by a business entity, partnership, corporation, association or any juridical person, the partner, president, director or manager who shall consent to or shall knowingly tolerate such violation shall be directly liable and responsible for the act of the employees and shall be criminally liable as a co-principal.

If the guilty officer is an alien, he shall be summarily deported after serving his sentence and shall be forever barred from re-entering the Philippines.

Sec. 20. Implementing Rules and Regulations. – Within sixty (60) days from the approval of this Act, the DOH, in consultation with the FDA, and other concerned agencies and stakeholders, shall promulgate the necessary implementing rules and regulations (IRR) for the effective implementation of this Act. Failure to promulgate the rules and regulations shall not prevent the implementation of this Act upon its effectivity.

Sec. 21. Separability Clause. – If any provision of this Act is declared unconstitutional or otherwise invalid, the validity of the other provisions shall not be affected thereby.

Sec. 22. Repealing Clause. – All laws, decrees, orders, rules and regulations or parts thereof inconsistent with this Act are hereby repealed or modified accordingly.

Sec. 23. Effectivity. – This Act shall take effect after fifteen (15) days from its publication in the *Official Gazette* or in a newspaper of general circulation.

Approved,