Tobacco and E-Cigarette Industry Interference in Public Health Policy in the Philippines
Executive Summary

The increasing popularity of electronic nicotine delivery systems (ENDS) or e-cigarettes in the Philippines puts Filipinos in danger of falling into another public health death trap. The World Health Organization (WHO) warns countries on the body of evidence about the health hazards posed by ENDS products and the unproven rhetoric that it is a viable “harm reduction” and/or “cessation tool.”

Recognizing the growing public health issue, the Philippine legislature saw the need to establish a regulatory system particular to ENDS. Pending bills for national regulation propose varying rules for ENDS sale, use, and marketing and, through industry and consumer groups, the ENDS industry has been aggressively lobbying for regulations favorable to their commercial interests, especially as regards product licensing and testing.

Through a comprehensive analysis of ENDS and tobacco industry interference in policy setting, triangulating mixed methodologies and data sources, this study shows that the tobacco industry, too, while discreet in terms of lobbying representation, has been a major actor for influencing policy formulation for ENDS in the Philippines.

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This study reveals that of the nine (9) bills proposing ENDS regulation in Congress, six (6) are oriented to adopting ENDS industry positions, thereby demonstrating industry origin or draftsmanship. More importantly, three (3) bills—two at the House of Representatives and one in the Senate—show the involvement of Philip Morris International (PMI).

In particular, these PMI-linked bills seek to pre-empt the regulation of heated tobacco products, especially its IQOS brand, and the approval of their health claims by regulatory bodies. This is the first observation globally of this unique strategy of tobacco industry interference.

Observations and documentation of tactics for the promotion of national and local measures for non-restrictive regulation of ENDS validate that there is a unity of interest between the ENDS industry and the tobacco industry. This implicates the government’s international legal obligation under Article 5.3 of the WHO Framework Convention on Tobacco Control (FCTC) and requires the critical vigilance public officials and public health advocates in all levels of legislative development, reform, and enforcement.

To this end, the bills that have ENDS and tobacco industry draftsmanship should be unequivocally rejected. Strategic multi-sectoral support should be initiated to strengthen accountability among members of the legislature towards the rejection of these tobacco industry proposals. Moreover, both industries, including their industry lobbyists and agents, must be removed from participation in legislative formulation, consistent with Article 5.3 of the FCTC. The protection, respect, and fulfillment of the right to health of the Filipino people demand that ENDS policy formulation must be free from the historically documented racketeering of the tobacco industry.
Since its introduction in the Philippine market, the use of electronic nicotine delivery systems or ENDS—more popularly known as “e-cigarettes” or “vape”—have become more and more popular among Filipinos. “Vape shops” have proliferated in major cities in the country and brands of ENDS and e-juice are now being marketed in major convenience stores.\(^1\)

The 2015 Global Adult Tobacco Survey estimates that there are around 550,000 current adult users of e-cigarettes in the country.\(^2\) Major ENDS trade associations have claimed membership of tens of thousands to a few million.\(^3\) This rise in the use of a largely unregulated class of products has gained the attention of policymakers in both the local and national levels, who have seen the need to restrict, regulate and control its use, sale, purchase, and advertisement, promotions and sponsorship to varying extents.

The rationale for such policies is founded on the increasing evidence of the risk profile of e-cigarettes, both with respect to the device itself and the solution or e-liquid.\(^4\) The health risks of ENDS products have been demonstrated across a wide range of scientific studies. The reports of the World Health Organization (WHO) have emphasized the need to take a precautionary approach—restricting or limiting use until their safety has been satisfactorily established.\(^5\) Despite these standards, the ENDS industry consistently takes a uniform position that e-cigarettes are an effective smoking cessation device and part of a harm reduction strategy.

The need for an informed, evidence-based regulation is clear considering standards setting and compliance issues with industry

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1. “ENDS, of which electronic cigarettes are the most common prototype, deliver an aerosol by heating a solution that users inhale. The main constituents of the solution by volume, in addition to nicotine when nicotine is present, are propylene glycol, with or without glycerol and flavouring agents.” *Electronic nicotine delivery systems*, Report by WHO, Provisional agenda item 4.4.2, Conference of Parties to the WHO Framework Convention on Tobacco Control, FCTC/COP/6/10 Rev.1 (Sept. 1, 2014). This paper uses the terms “ENDS,” “ENDS products,” or “e-cigarettes” interchangeably. ENDS products are more colloquially called “vape/s,” with users called “vaper/s” and the act, “vaping.”

2. Based on the estimated 0.8% prevalence rate of current users of e-cigarettes. An estimated 2.8% reported having used e-cigarettes. See Department of Health (DOH) & Philippine Statistics Authority. Global Adult Tobacco Survey: Country Report 2015, at p. 102.


“self-regulation” especially in meeting the demands of public health protection. In the Philippines, considering the absence of national special legislation that standardizes ENDS product control and monitoring, the legal regime permits restriction or regulation at the local level. Several local government units (LGUs)—cities and municipalities—have, therefore, restricted the trade and use of ENDS, with some localities treating these products in the same manner as tobacco products or with a distinct regulatory framework.

At the national level, the current 17th Congress has also seen seven bills filed before the House of Representatives (HOR) and two in the Senate that aim to create a country-wide regulatory regime for ENDS as of July 2018. In both settings, ENDS industry participation has been observed.

In both local and global markets, traditional tobacco companies (TTCs) have taken interest of the expanding ENDS industry and have themselves diversified to penetrate the ENDS market. A popular foreign e-cigarette brand, VUSE, is owned by R.J. Reynolds Vapor Company, a subsidiary of the tobacco giant, Reynolds America. British American Tobacco (BAT), the largest tobacco company in the Europe, launched Vype around four years ago. Altria Group (formerly, Phillip Morris Companies, Inc.) owns MarkTen. Lorillard paid $135 million for Blu, but when R.J. Reynolds bought that tobacco company in 2015, its e-cigarette brand was sold to Imperial Tobacco, a company in the United Kingdom.

In of light this established and increasing involvement of the tobacco industry in ENDS manufacturing and trade, their participation...
in policy setting and implementation raises important legal issues. Specifically, the Philippines adheres to Article 5.3 of the WHO Framework Convention on Tobacco Control (FCTC), which provides that “[i]n setting and implementing their public health policies with respect to tobacco control, [countries] shall act to protect these policies from commercial and other vested interests of the tobacco industry in accordance with national law.” This stems from fact that there is a fundamental and irreconcilable conflict between the tobacco industry’s interests and public health policy interests.14

Internal tobacco industry documents have revealed standard tobacco tactics historically employed by the industry to thwart, weaken, and delay the development and implementation of public health policies which adversely impacts its business interests.15 In United States v. Philip Morris USA Inc.,16 for instance, the United States District Court of the District of Columbia, found that tobacco companies: “have marketed and sold their lethal product with zeal, with deception, with a single-minded focus on their financial success, and without regard for the human tragedy or social costs that success exacted.”

Electronic Nicotine Delivery Systems and Electronic Non-Nicotine Delivery Systems (ENDS/ENNDS) is a major threat to tobacco control.17 Public health experts have argued that TTCs are marketing ENDS in order to minimize the threat to tobacco sales by promoting ENDS as a complement rather than an alternative to tobacco, or controlling technological innovations that would prevent improvements in their efficacy as an aid to cessation; promote smoking through ENDS advertising and promotion to adults and children; assert potential benefits of ENDS—and, in the near future, nicotine inhaler technology—as an excuse to engage with and influence policymakers, scientists, and advocates in tobacco control with a view to undermining the WHO FCTC, while at the same time building credibility through corporate social responsibility initiatives.18

These demonstrable objectives directly question the underpinning reasons why the ENDS industry has been including itself in venues and forums for policy development. For the government to allow the ENDS industry to participate in policy development and implementation knowing that their main agenda is to promote, protect, and preserve

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14 See WHO FCTC Conference of Parties, Guidelines for implementation of Article 5.3 of the WHO Framework Convention on Tobacco Control on the protection of public health policies with respect to tobacco control from commercial and other vested interests of the tobacco industry, Principle 1.


17 Peeters S, Gilmore AB. Understanding the emergence of the tobacco industry’s use of the term tobacco harm reduction in order to infirm public health policy. Tobacco Control 2015;24:182-189.

their and the tobacco industry’s commercial and vested interest runs contrary to the constitutional obligation of the government to prioritize the human rights to life and health over proprietary privileges. This becomes even more critical in a country considered to have the “strongest tobacco lobby in Asia,” because of the broad governance—and, ultimately, public welfare—implications.

Moreover, the fierce and relentless opposition from the e-cigarette industry to specific or restrictive regulations intended to evaluate the safety of the product for public consumption runs counter to their own claims that ENDS has some therapeutic benefits as a smoking cessation tool or harm reduction device. This apparent duplicity in position must be subjected to close scrutiny. Policy makers and implementers, in developing comprehensive policies restricting ENDS products, must ensure that its public health objective is not diminished by the commercial and vested interest of the industry.

21 In the Articles of Incorporation of the Philippine E-Cigarette Industry Association, Inc., for instance, it is expressed that “[a]ssociation members agree that they will not: assert any claims regarding the health or safety of the product” and “make any smoking cessation claims.” Contrary to this position, the domestic ENDS industry has been advocating for ENDS as a smoking cessation measure, see, e.g., Study data on alternatives to smoking, DOH told, Philippine Daily Inquirer (14 November 2017), http://newsinfo.inquirer.net/945105/study-data-on-alternatives-to-smoking-doh-told.
The goal of this study is limited to a description of tactics used by the tobacco industry through or with the ENDS industry to interfere in the development and implementation of public health policies restricting ENDS products at the national and local government levels. In particular, it sought to characterize the forms of interference done based on WHO typology,22 with attention given to the domain of “lobbying” in the Philippine legislature. Policy options as regards other facets of regulations are not covered by this paper.

As a rapid appraisal with a short-term study period, the study maximized the utilization of mixed methods that triangulated comprehensive literature review, interviews, and field or observational visits. Literature review comprised of industry documents such as publicized position papers, press releases and public statements, social media posts, and public organizational filings such as Articles of Incorporation and By-Laws with the Philippine Securities and Exchange Commission. At least one of the authors were also present during local and national public sessions on ENDS regulation, which aided in contextualizing minutes of the legislative sessions and debates in both the House of Representatives and Senate and the local legislative councils.

Figure 1. A “vape lounge” (left) and e-juice selection (right). Vape lounges have become a dominant mode of ENDS retail, together with mall-based kiosks, convenient stores, and online sites.

22 The tactics are classified as follows (not mutually exclusive): intelligence gathering; public relations; political funding; lobbying; consultancy; funding research, including universities; smokers’ rights groups; creating alliances and front groups; intimidation; philanthropy; corporate social responsibility; youth smoking prevention and retailer education programmes; litigation; smuggling; international treaties and other international instruments; joint manufacturing and licensing agreements and voluntary policy agreements with governments; and pre-emption. WHO, Tobacco industry interference with tobacco control (2008), 12-13.
of Baguio City and Quezon City. All bills filed in both the House of Representatives and Senate, up to September 2018, were subjected to legal and content analysis.

Interviews were also conducted with government officials, members of civil society organizations, and local and regional experts in public health and tobacco control to identify and scope forms of industry interference, examine industry intimidation tactics against public health advocates, and evaluate ENDS industry compliance with the rules promulgated by regulatory agencies such as the Department of Health (DOH) and Food and Drug Administration (FDA). Finally, field visits and observational studies were conducted in 30 vape shops, kiosks, and convenience stores (e.g., as shown in Figure 1) in Metro Manila to survey product diversity and extent of access restrictions, and informal interviews were conducted with shop owners, ENDS retailers, and ENDS users.
Agents of ENDS Industry Interference

To characterize ENDS industry interference in the Philippines, it is critical to describe the agents behind this. While the tobacco industry’s e-cigarette products are available in the market, the companies are not visible in public debates on e-cigarettes. Instead, the vaping community is in the forefront championing the issue. Their views are represented by three main groups: the Philippine E-Cigarette Industry Association (PECIA), the Philippine E-Liquid Manufacturers Association, Inc. (PEMA), and The Vapers Philippines (TVP).

Industry Associations: PECIA and PEMA

The PECIA has been the leading lobbying arm of the ENDS industry and has been described as its “umbrella” organization. Terms of legislative deliberation participation at the national and local levels, PECIA’s presence has been uniform and consistent. Its representatives have attended legislative sessions in both the House of Representatives and the Senate regarding ENDS regulatory bills, as well as local legislative sessions for ordinance development of various LGUs, including Quezon City, Makati City, Navotas City, Pasay City, Antipolo City, and Baguio City. The letters that they send to LGUs with pending or prospective ENDS-related ordinance indicate that PECIA closely monitors the introduction of regulatory policies.

Apart from legislative lobbying, PECIA has also submitted its positions to the Office of the President regarding the proposed “National Smoking Ban” (which led to Executive Order No. 26, series of 2017) and the Office of the Secretary on Trade and Industry. PECIA is currently led by its President, Joey Dulay, a proprietor of ENDS retailer, Green Puff Electronic Cigarettes, Inc.

PECIA was incorporated on April 2013, as a non-stock corporation intended as an industry trade association of electronic cigarette companies to promote and institute industry-wide standards and a code of conduct, maintain sound professional practices, and ensure the proper use of electronic cigarette

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24 These activities are documented in PECIA’s Facebook page: https://web.facebook.com/PECIAI. At least one of the authors or representative/s of HealthJustice has also attended at least one public session of these ordinances as observer or as resource person.
25 Letter of PECIA dated 22 November 2016 (Request that e-cigarettes be excluded in the meantime from the coverage of the proposed Executive Order on public smoking particularly on the provision that vapers and smokers share the same restrictions) and received on 24 November 2016 by the Office of the Executive Secretary; Letter to President Rodrigo Duterte dated and received 19 July 2017.
26 Letter to Secretary Ramon M. Lopez received 29 July 2016.
27 Mr. Dulay’s social media accounts in Facebook and LinkedIn show that he is the President and CEO of Green Puff Electronic Cigarettes, Inc. The retailer lists nine stores located in various malls in Metro Manila.
28 Articles of Incorporation obtained from the Securities and Exchange Commission.
technologies.” In becoming a part of the organization, “[a]ssociation members agree that they will not: assert any claims regarding the health or safety of the product[,] make any smoking cessation claims, or sell or market their products to minors.” Contrary to this term, claims of “tobacco harm reduction” or “smoking cessation” aids have, however, been prevalent and persistent as arguments forwarded by PECIA and its members during legislative deliberations.

PECIA is an active proponent and advocate of “self-regulation” of the domestic ENDS industry and vehemently opposes the regulatory jurisdiction of the FDA but welcomes regulation by the DTI, solely for the purpose of testing their products’ safety. Public health advocates have opposed this proposal due to the proliferation of misleading product marketing that has resulted from the current “self-regulation” approach (see Figure 2).

During legislative deliberations and in its position papers, it has cautioned the government against banning ENDS sale and use, claiming that the same would deprive

Figure 2. E-juice products with misleading descriptors: (left) the “may contain nicotine” leaves consumers at a loss whether the e-juice contains nicotine and the statement “swag and awesomeness” in the ingredients listing particularly appeals to youth; (right) the “low nic” descriptor conceals true nicotine concentration.

29 PECIA Articles of Incorporation, Art. II(1).
30 Id.
smokers and non-smokers alike of the “right to choose a better alternative to tobacco products.” It has also repeatedly emphasized, in its public postings and during legislative debates, that e-cigarettes are “safer alternatives to smoking.” PECIA maintains that e-cigarettes should not be treated similarly to tobacco products because “they do not contain tobacco.” Furthermore, as allegedly “safer alternatives to tobacco products,” PECIA labels itself as “[o]ne community fighting for the right to make healthy choices” and argues that individuals have the “right to vape.”

Another industry group is PEMA, an association of local e-liquid manufacturers whose goal is to standardize e-liquid manufacturing. It is a member of PECIA and has been working with PECIA, as well as ENDS consumer groups, in “business meeting[s] and planning” to create a unified position in promoting the ENDS industry. PEMA’s President is Edward Gatchalian, who is a proprietor of a local e-liquid company, Holy Smokes! ELiquids, Inc.

Since both leaders of PECIA and PEMA have ENDS businesses, their substantial investments therein result to clear, undisputable conflicts of interests that puts into question their standing and position to suggest regulatory amendments that affect public health and the general welfare. The same can be said for consumer groups that are supported by, or work in close coordination with, the ENDS industry.

Consumers Groups: TVP and informal groups

ENDS consumers have organized lobby groups to promote ENDS use, with clear indications of PECIA and PEMA support. Two organizations have been prominent in this respect: (1) The Vapers Philippines (TVP) and (2) the Vapers Association of the Philippines (VAP).

TVP claims to be “a consumer advocacy group with more than a thousand members all over the Philippines.” It advocates for what it believes would be “reasonable” ENDS regulation in the Philippines and allegedly aims to “educate the public about the

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31 See, e.g., PECIA’s Facebook posts of 25 January 2017 and 27 November 2016.
32 From http://holysmokesinc.com/about-us/.
34 As shown in PECIA’s 3 July 2016 Facebook post.
36 The company claims to be “one of the most well known, proven, and trusted brand of eliquids locally and internationally up to this day” and “are a duly registered and certified company with a dedicated and up-to-par operation supervised daily.” http://holysmokesinc.com/wholesale/#why-choose-us
37 “The tobacco industry produces and promotes a product that has been proven scientifically to be addictive, to cause disease and death and to give rise to a variety of social ills, including increased poverty. Therefore, Parties should protect the formulation and implementation of public health policies for tobacco control from the tobacco industry to the greatest extent possible.” Guidelines for implementation of Article 5.3 of the WHO Framework Convention on Tobacco Control on the protection of public health policies with respect to tobacco control from commercial and other vested interests of the tobacco industry, 113.
distinction between e-cigarettes and regular tobacco products and the former’s potential as a safer product.”

TVP’s membership in the International Network of Nicotine Consumers Organizations (INNCO) provides it with technical assistance in lobbying for ENDS regulation in the country. The broad organizational goals of INNCO align with general tobacco industry normalization rhetoric of “honest evidence on safer nicotine products and the principles of tobacco risk reduction.”

Informal, less organized groups like the Vapers Association of the Philippines have also been created to distribute pro-ENDS messaging to consumers, as well as foster a united front for “responsible” use of ENDS products.

E-Cigarette Industry Interference Tactics

1. Participation in National Legislative Development

Currently, there are nine (9) bills filed in both the House of the Representatives (HOR) and the Senate of the Philippines for the regulation of e-cigarettes. Seven (7) bills have been filed before HOR: HB 532, HB 3330, HB 4325, HB 4810, HB 7289, HB 7935, and HB 7883. In the Senate, two (2) bills have been filed: SB 1538 and SB 1774.

Moreover, two House Resolutions have been filed in the HOR: HR 973 and HR 1885, which were favorably endorsed by both chairs of the HOR Committee on Trade and Industry and Committee on Health.

9 Quoted and retrieved from https://innco.org/our-members/the-vapers-philippines.
40 The goals are: (a) The recognition of the relative safety of smoke free nicotine products. (b) The need to avoid disproportionate regulation on the manufacture, distribution and the (overly) restrictive consumer access to these products. (c) The taxation of products as consumer goods, with no tobacco duties or excises applied. (d) That any restrictions on use in public areas and work spaces are justified on the basis of verifiable evidence. (e) Any decisions made to restrict or limit the use of alternative nicotine products in private premises should be left to individual owners/managers. (f) That there should be no bans on the sale, supply, possession and use of safer forms of smokeless tobacco (e.g. snus), vaping products and E-Liquid containing nicotine, and where currently illegal they should be made legal. https://innco.org/about-us.
42 From https://web.facebook.com/groups/VapersAssociationofthePhils/about/.
43 An Act Regulating the Packaging, Use, Sale, Distribution, and Advertisements of Electronic Smoking Devices, Amending for the Purpose Republic Act No. 9211, Otherwise Known as the Tobacco Regulation Act of 2003, and For Other Purposes (filed by Representatives Rodel M. Batocabe, Alfredo A. Garbin, Jr., and Christopher S. Co on 30 June 2016).
44 Vaporized Nicotine Product Act of 2016 (filed by Representatives Rodel M. Batocabe, Alfredo A. Garbin, Jr., and Christopher S. Co on 25 August 2016).
45 E-Cigarette or Vape Regulation Act of 2016 (filed by Representative Eric L. Olivarez on 8 November 2016).
46 ENDS Regulation Act (filed by Representative Rufino B. Biazon on 23 January 2017).
47 Vaporized Nicotine Product Regulation Act of 2016 (filed by Representative Victoria Isabel G. Noel on 27 February 2018).
48 An Act Regulating Electronic Cigarettes (filed by Representative Luis Raymund F. Villafuerte, Jr.).
49 An Act Regulating Electronic Cigarettes (filed by Representative Robert Ace S. Barbers).
50 An Act Regulating Vaporized Nicotine Products (filed by Senator Vicente C. Sotto III on 2 August 2017).
52 A Resolution Expressing the Sense of the House of Representatives in Urging the Department of Health to Adopt Harm Reduction Measures Particularly the Use of Electronic Cigarettes as an Alternative for Smokers as Part of its National Smoking Control Strategy (filed by Representative Anthony M. Bravo on 8 May 2017).
53 A Resolution Urging the Department of Health to Promote Harm Reduction Strategies, As Part of Its National Tobacco Control Strategy, Particularly the Use of Electronic Cigarettes as an Alternative for Smokers (filed by Representatives Anthony M. Bravo and Jose “Pingping” I. Tejada).
54 Committee Report No. 735 dated 16 May 2018.
These bills describe ENDS products in various terminologies, such as “electronic smoking device” for HB 532, “vaporized nicotine products” for HB 3330, HB 7289, and SB 1538, and ENDS or e-cigarettes for HB 4325, HB 4810, HB 7935, HB 7993, and SB 1774 (see Table 1).

Regulation of ENDS generally falls across several domains, namely: prohibition of use; access restrictions for minors; health warnings in packages; obligations of point-of-sale establishments; advertisement, promotions, and sponsorship; and product registration, testing, and licensing. The bills also differ in the proposed administrative agency with primary regulatory authority over ENDS products. Regulation is seen lodged with, for instance, (1) the Inter-Agency Committee-Tobacco (IAC-T) under the Tobacco Regulation Act, which currently regulates various aspects of tobacco product

Table 1. General Comparison of Regulatory Design of ENDS Bills filed in the

<table>
<thead>
<tr>
<th>Title</th>
<th>ENDS</th>
<th>Date of Filing</th>
<th>General Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>An Act ... Amending ... Republic Act No. 9211</td>
<td>Electronic smoking device</td>
<td>30 June 2016</td>
<td>Requires registration under the FDA</td>
</tr>
<tr>
<td>&quot;E-Cigarettes or Vape Regulation Act of 2016&quot;</td>
<td>Electronic cigarettes or e-cigarettes</td>
<td>8 Nov 2016</td>
<td>Requires FDA to assess “reduced risk” and “reduced exposure” applications</td>
</tr>
<tr>
<td>&quot;ENDS Regulation Act&quot;</td>
<td>Electronic nicotine delivery systems</td>
<td>23 Jan 2017</td>
<td>Requires only product registration in the Department of Trade and Industry (DTI)</td>
</tr>
<tr>
<td>&quot;Vaporized Nicotine Product Regulation Act of 2016&quot;</td>
<td>Vaporized nicotine product</td>
<td>25 Aug 2016</td>
<td>Loosens FDA regulation to approval of health claims</td>
</tr>
<tr>
<td>&quot;Vaporized Nicotine Products Regulations Act&quot;</td>
<td></td>
<td>2 Aug 2017</td>
<td>Requires FDA to assess &quot;reduced risk&quot; and &quot;reduced exposure&quot; applications</td>
</tr>
<tr>
<td>&quot;Vaporized Nicotine Product Regulation Act of 2016&quot;</td>
<td></td>
<td>27 Feb 2018</td>
<td>Requires only product registration in the Department of Trade and Industry (DTI)</td>
</tr>
<tr>
<td>&quot;E-Cigarette Regulation Act of 2018&quot;</td>
<td>Electronic cigarettes or e-cigarettes</td>
<td>14 Mar 2018</td>
<td>Removes FDA jurisdiction</td>
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<td></td>
<td></td>
<td>19 July 2018</td>
<td>Places product regulation under DTI (Bureau of Product Standards)</td>
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<td></td>
<td></td>
<td>1 Aug 2018</td>
<td></td>
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</tbody>
</table>

* Columns in red are bills with indications of PMI draftsmanship based on IQOS-favorable regulation; columns in orange are bills with indications of general ENDS industry draftsmanship based on orientation with policy positions.
During legislative deliberations, it was clear that the ENDS industry has recognized the need to influence legislative policy towards a weaker set of regulation, as compared to the existing regulation under the DOH and FDA (see Box 1), and has vigorously advocated for pro-industry positions during these bills’ respective debates.

Box 1. Current Regulatory Framework for ENDS in the Philippines

ENDS regulation is imbued with public interest because of e-cigarettes’ rapidly increasing use and popularity as a consumer product and the increasing scientific evidence of their health risks.55 The high abuse and dependence potential of nicotine, the lack of access restrictions to the youth, and the ENDS industry’s claims that they are harm reduction and smoking cessation devices further underscore the necessity of comprehensive regulation as an exercise of police power.56 This is consistent with Section 15, Article II of the Philippine Constitution, which provides that is the duty of the State to protect and promote the right to health of the people and instill health consciousness among them.

In particular, three laws apply in concert in setting a broad regulatory regime for ENDS that establishes the authority of the DOH and FDA: (1) Republic Act No. (R.A.) 7394 or the Consumers Act of the Philippines, (2) the Administrative Code, and (3) R.A. 9711 or the FDA Act of 2009.

Under the Consumer Act of the Philippines, the DOH has implementing authority “with respect to food, drugs, cosmetics, devices and substances.”57 Under the definitions of this law, the ENDS vaporizer falls within the operative definition of a device,58 while e-juice falls within the definition of drugs.59 Under the Consumer Act, the DOH, therefore, may regulate ENDS by establishing standards and quality measures for both e-juice and device.60

This regulatory role of the DOH also stems

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56 “The promotion of public health is a fundamental obligation of the State. The health of the people is a primordial governmental concern.” Beltran v. Secretary of Health, G.R. No. 133640 (Philippine Supreme Court En Banc), Nov. 25, 2005.
57 Art. 6(a). See also art. 20-22.
58 “Device means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part or accessory which is ... intended to affect the structure or any function of the body of man or other animals, and which does not achieve any of its principal intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its principal intended purposes.” Art. 4(ab).
59 “Drugs mean ... articles (other than food) intended to affect the structure or any function of the body of man or animals.” Art. 4(ad).
60 Art. 21(a).
from its authority from the Administrative Code. The Administrative Code provides that
the DOH shall define the national health policy and implement a national health plan within
the framework of the government’s general policies and plans,61 and issue orders and
regulations concerning the implementation of established health policies.62 This is
reiterated in Executive Order No. 102, series of 1999,63 which mandates the DOH to formulate
national policies and standards for health64 and as lead agency in ensuring equity, access
and quality of health care services through policy formulation, standards development
and regulations.65

Pursuant to these mandates, the DOH issued Administrative Order No. (AO) 2014-0008,
Rules and Regulations on Electronic Nicotine Delivery System (ENDS) or Electronic
Cigarettes, on March 12, 2014. The Order classified ENDS as combination drug and
medical devices,68 which meant that ENDS “shall be regulated as medicinal product.”
69 Under this regulation, “ENDS [must] pass the safety, efficacy and quality evaluation
of the FDA before a market authorization is issued as health product and health-related
device.”70 Furthermore, the Order required all ENDS manufacturers and distributors to
secure a license to operate from FDA and a Certificate of Product Registration (CPR).71
Without a CPR, a product may not be used or offered for sale.72

Despite this AO, however, during the Senate Committee on Health and Demography
and Committee on Trade, Commerce and Entrepreneurship joint hearing for Senate

61 Book 4, Title IX, ch. 1, §1.
62 Book 4, Title IX, ch. 1, §9.
64 §3(a).
65 §2(e).
66 §§3, 5 (amending Section 4 of Republic Act No. 3720).
67 “Health products means food, drugs, cosmetics, devices, biologicals, vaccines, in-vitro diagnostic reagents and household/urban hazardous
substances and/or a combination of and/or a derivative thereof. It shall also refer to products that may have an effect on health which require
regulations as determined by the FDA.” §9.
68 ¶1, Art. V.
69 Id.
70 ¶2, Art. V.
71 Art. II.
72 ¶5, Art. V
Bill No. 1538[^73] last 29 March 2018, the FDA Director General confirmed that there was no manufacturer or distributor of ENDS that has applied with FDA for accreditation.[^74] The FDA recently stated that all ENDS products in the Philippine market are “technically illegal.”[^75]

The non-enforcement of the current regulations allows the industry leeway in mobilizing industry allies in the legislature, who are sympathetic to the position that ENDS are “safer alternatives” to tobacco products. Thus, in the House of Representatives, three (3) bills[^76] have been filed that aim to “balance the interest of the State in promoting public health and the industry’s right to trade.” In the same manner, the two (2) bills filed before the Senate for ENDS regulation, both aim to introduce more lenient regulatory frameworks and divest or loosen FDA authority for ENDS products.

In light of the strict requirements under FDA regulation, too, the ENDS industry has supported positions to transfer exclusive or primary regulation to the DTI. However, the DTI’s jurisdiction under the Consumer Act is on consumer products, described as prime commodities or basic necessities such as food, cement, steel, bottled water, canned sardines, candles, toiletries, laundry soap, and the like. This jurisdiction was confirmed during the hearing for SB No. 1538, where an Undersecretary of DTI expressly declared that e-cigarettes are not prime commodities requiring the exercise of its regulatory function under the Consumer Act of the Philippines.[^77]

Currently, the ENDS industry has tapped the National Tobacco Administration (NTA) for testing its products for safety, despite the lack of legal mandate as a proper regulatory authority for such products. The NTA’s mandates are, principally, to improve the economic and living conditions and raise the quality of life of the tobacco farmers, including those who depend upon the industry for their livelihood, and to promote the balanced and integrated growth and development of the tobacco industry to help make agriculture a solid base for industrialization.[^78]

[^73]: An Act Regulating Vaporized Nicotine Products.
[^74]: Minutes, p. 72.
[^76]: HB 532, HB 3330, and HB 7289.
[^77]: Transcript of the Senate Hearing conducted on 19 March 2018; Author was present during the said hearing, p. 57.
[^78]: Section 33 of Republic Act No. 9211 or the Tobacco Regulation Act of 2003 also mandates the NTA to implement projects to free tobacco farmers from tobacco production through development of alternative livelihood programs. This is the legislative intent behind the “balanced policy” requirement of the Tobacco Regulation Act. See Nadate AC, Magtibay LS. Killing Smoking: Abrogating Tobacco Use Privileges and Trade Interests in Local Government Jurisdictions. Ateneo Law J 2017;62(2):499-533.
Indicia of Tobacco Industry Draftsmanship

Critically, the regulatory set-up proposed by HB 3330, HB 7289, and SB 1538 undermines current tobacco control measures that are in place and would benefit the tobacco industry the most.

For instance, as Table 2 shows, the bills define ENDS products as “a product with or without

Table 2. Comparison of Definitions of ENDS Products

<table>
<thead>
<tr>
<th>Definition of ENDS</th>
<th>HB No. 532 4325</th>
<th>HB No. 4810</th>
<th>HB No. 7289</th>
<th>HB No. 3330</th>
<th>SB No. 1538</th>
<th>SB No. 1744</th>
<th>SB No. 7935</th>
<th>HB No. 7993</th>
</tr>
</thead>
<tbody>
<tr>
<td>“Refers to an electronic device or a battery-powered vaporizer that can be used to deliver nicotine or other substances to the person inhaling from the device, including, but is not limited to, an electronic cigarette, cigar, or pipe.”</td>
<td>“[D]evices, often resembling cigarettes, cigars or pipes, designed to delivery nicotine or related substances to users in the form of a vapor. It is also known as electronic nicotine delivery systems (ENDS).”</td>
<td>“[E]ncompasses products that contain tobacco-derived substances, but in which tobacco is not necessary for operation. They are battery-powered devices that provide inhaled doses of nicotine or other substances by delivering a vaporized propylene glycol/nicotine mixture.”</td>
<td>“[M]eans 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. For avoidance of doubt, Vaporized Nicotine Products with tobacco shall not be considered cigarettes and shall not be covered by Republic Act No. 9211 or the Tobacco Regulation Act of 2003.”</td>
<td>“[M]eans a product with or without tobacco that generates a nicotine-containing aerosol without combustion, with or without electronics or any component of that products, this includes but is not limited to a cartridge, a tank and the device without a cartridge or tank.”</td>
<td>“[R]efers to a product that can be used for the consumption of a nicotine-containing vapor.”</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

* Columns in red are bills with indications of PMI draftsmanship based on IQOS-favorable regulation.
“Tobacco and E-Cigarette Industry Interference in Public Health Policy in the Philippines

Tobacco and E-Cigarette Industry Interference in Public Health Policy in the Philippines

20

This removal is even made express in HB 7289, which states that ENDS “shall not be considered cigarettes and shall not be covered by Republic Act No. 9211.”

They also exclude tobacco products characterized as ENDS from the ambit of the Republic Act No. 10643 or the Graphic Health Warnings Law of 2014 and has the potential to mainstream advertising, promotions, and sponsorships of ENDS products under the premise of “targeted communications,” which they do not prohibit. Specifically, the three bills expressly allow advertisements of ENDS products “at points-of-sales, through direct marketing, and on the internet.”

The enumeration of a limited number of areas where ENDS use in these bills prohibited also ensures their permissibility in all other areas. In particular, these bills only prohibit ENDS use in “places of worship, hospitals or other healthcare services, public conveyances, government offices, and educational or recreational facilities exclusively intended for minors,” but expressly allows the same “in all other enclosed places that are open to the general public, private workplaces and those places not covered in the preceding enumeration.”

Moreover, the three bills introduce the concepts of “reduced exposure claim” and “reduced risk claim” in ENDS regulation, patterned after the U.S. FDA’s Modified Risk Tobacco Product (MRTP) Applications system (see Table 3). The appearance of this novel regulatory set-up is important considering that PMI has applied for these claims in the United States for IQOS and, if approved, PMI could represent in its labels, packaging, or advertising that its product presents a lower risk of tobacco-related diseases or is less harmful than commercially marketed tobacco products.

However, the definitions of “reduced exposure claim” and “reduced risk claim” in the three bills appear to be particularized or based

80 See HB 3330, §3(a); HB 7289, §3(a); SB 1538, §3(a).
81 §3(a).
82 §3(a) of HB 7289.
83 See HB 3330, §5; HB 7289, §5; SB 1538, §5.
84 See HB 3330, §9(h); HB 7289, §9(h); SB 1538, §9(h).
85 See HB 3330, §9; HB 7289, §9; SB 1538, §9.
86 See HB 3330, §11; HB 7289, §11; SB 1538, §11.
87 See HB 3330, §§14(b), 15; HB 7289, §§14(b), 15; SB 1538, §§14(b), 15.
88 Id.
89 The U.S. FDA can issue an order authorizing the marketing of a MRTP only if the evidence submitted in the application meets the requirements of Section 911 of the Federal Food, Drug and Cosmetic Act. An MRTP application must demonstrate that the product will or is expected to benefit the health of the population as a whole. See U.S. FDA, Guidance for Industry, Modified Risk Tobacco Product Applications Draft Guidance, https://www.fda.gov/downloads/TobaccoProducts/Labeling/RulesRegulationsGuidance/UCM297751.pdf.
91 See, e.g., SB 1538, §15(a).
92 See, e.g., SB 1538, §15(b).
from pharmacological and human studies already conducted for IQOS in PMI’s U.S. FDA Modified Risk Tobacco Product regulation, as shown in Table 3.

Table 3. Comparison of proposed statutory definitions and PMI’s IQOS tests in its U.S. FDA MRTP application*

<table>
<thead>
<tr>
<th>Reduced Exposure Claim</th>
<th>Reduced Risk Claim</th>
<th>PMI IQOS Application</th>
</tr>
</thead>
<tbody>
<tr>
<td>The manufacturer characterizes the levels of nicotine uptake from vaporized nicotine products compared to cigarette smoking based on clinical trials.</td>
<td>The manufacturer can support the claim with clinical studies. 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 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. (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.</td>
<td>PMI conducted at least four studies on reduced exposure clinical trials with at least seven days study period. For instance, PMI conducted two “randomized, open-label, parallel group reduced exposure studies included [IQOS] (ad libitum use), [conventional cigarettes] (ad libitum use), and smoking abstinence (SA) arms with a five day investigational exposure period which was subsequent to a 2 day baseline period during which all the subjects smoked their own brand of CC.” The aim of these studies was “to demonstrate reduction in the levels of biomarkers of exposure (BoExp) to selected harmful and potentially harmful constituents (HPHCs) following switching to THS in an optimal, clinical setting where compliance to arm allocation was controlled by the site staff.” PMI conducted perception and behavioral assessment studies including usability and comprehension studies. PMI’s studies were “conducted in accordance with the Guidelines”</td>
</tr>
</tbody>
</table>

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 harmful and potentially harmful constituents (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.

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

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95 See: Philip Morris Products S.A. PMI Research & Development, THS 7.3.1 Executive Summary – Clinical studies, https://digitalmedia.hhs.gov/tobacco/static/mrtpa/731clin/11%207.3.1%20TabIndex_Clinical_Redacted%2028229.pdf.

96 Id., at p. 1.

97 Id.

98 See: Section 7.3.2 in https://www.fda.gov/TobaccoProducts/Labeling/MarketingandAdvertising/ucm586657.htm#2.
### Reduced Exposure Claim
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.

### Reduced Risk Claim
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.

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

### PMI IQOS Application
for Good Epidemiological Practice and was approved by institutional ethical review boards.99

PMI conducted a randomized, controlled, open-label, 3-arm parallel group, multi-center study *to demonstrate reductions in exposure to selected smoke constituents in apparently healthy smokers switching to the [IQOS] or observing smoking abstinence, compared to continuing to use menthol conventional cigarettes, for 5 days in confinement and prolonged by 86 days in an ambulatory setting.*100

PMI ostensibly utilizes the term “biomarkers of exposure” in its studies. In its 90-day reduced exposure studies, “biomarkers of exposure” reduced at 48-53% for carboxyhemoglobin; 81% for monohydroxybutenyl mercapturic acid; 61-65% for 3-hydroxypropylmercapturic acid; and 81-87% for S-phenylmercapturic acid (at Day 90).101

Apart from clinical studies, clinical risk “endpoints” are reflected in PMI’s study, entitled “Analysis of Whole Offer Test Data Japan, Italy, Germany, Switzerland and South Korea”, which proxies smoking cessation with exclusive use (“switch to”) of IQOS. Post-market surveillance and studies have been conducted by PMI in its MRTP application.103

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* Criteria in parenthesis are alternative criteria under the proposed law. Emphasis supplied.

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100 Philip Morris Products S.A. PMI Research & Development, THS 7.3.1 Tabulated Index – Clinical studies, https://digitalmedia.hhs.gov/tobacco/static/mrtpa/731clin/10%207.3.1%20TabIndex_Clinical_Redacted%20%281%29.pdf.
101 See: Philip Morris Products S.A. PMI Research & Development, THS 2.7 Executive Summary, Table 8: Summary of 90-Day Reduced Exposure Studies: Reduction of the Primary BoExp at Day 5 and Day 90 [100-(THS:CC) ratio and 100-(SA:CC) ratio in %], at p. 82, https://www.fda.gov/downloads/TobaccoProducts/Labeling/MarketingandAdvertising/UCM560044.pdf.
102 See: https://www.accessdata.fda.gov/Static/widgets/tobacco/MRTP/PMP/73%20HUMAN.zip.
103 See: https://www.fda.gov/TobaccoProducts/Labeling/MarketingandAdvertising/ucm546281.htm#8.
This set of definitions risks limiting the quasi-legislative and quasi-judicial authorities of the Philippine FDA in determining whether future applications for such claims may be approved as it precisely pre-empts approval by the definitions sought to be introduced\textsuperscript{104} or opens the FDA to litigation.\textsuperscript{105} PMI’s regulatory pre-emption through these bills provides it with substantial control, dominance, and monopoly over this product line.

Table 4. Comparison of Provisions on Modified Risk Claims

<table>
<thead>
<tr>
<th>Bills filed Regulating ENDS in the 17th Congress (up to Sept. 2018)*</th>
<th>Health Claims Regulation</th>
</tr>
</thead>
<tbody>
<tr>
<td>HB No. 532</td>
<td>HB No. 4325</td>
</tr>
<tr>
<td>---------------------------------------------------------------</td>
<td>--------------------------</td>
</tr>
<tr>
<td>Health Claims Regulation</td>
<td>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 FDA.</td>
</tr>
<tr>
<td>* 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 harmful and potentially harmful constituents.</td>
<td></td>
</tr>
<tr>
<td>** 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.</td>
<td></td>
</tr>
</tbody>
</table>

\textsuperscript{104} "Administrative agencies possess ... the power to make rules and regulations that results in delegated legislation that is within the confines of the granting statute. ... The administrative body exercises its quasi-judicial power when it performs in a judicial manner an act that is essential of an executive or administrative nature, where the power to act in such manner is incidental to or reasonably necessary for the performance of the executive or administrative duty entrusted to it." Palawan Council for Sustainable Development v. Bonanza Air Services, G.R. No. 183173, Aug. 24, 2016.

\textsuperscript{105} Through a mandamus petition "to compel action and to coerce the performance of a pre-existing duty." Special People, Inc. Foundation v. Canda, G.R. No. 160932, Jan. 14, 2013. The definitions in the bills transform regulatory prerogative from a discretionary review or judgment into a ministerial function, owing to the pre-emption afforded by the legal or statutory authority itself.
This similarity of the rationale for the proposed provisions strongly indicates that this will favor IQOS and similar products owned by the tobacco industry which may later on be fully or formally introduced in the Philippine market. Currently, IQOS are already sold in mall-based kiosks like leading retailers Fuma\(^{106}\) and Lighters Galore,\(^ {107}\) where ENDS are sold together with various brands of cigarettes, cigars, smokeless tobacco, and smoking accessories. They are also sold through online retail stores, which have become a popular mode of purchasing ENDS products, and include general online retailers\(^ {108}\) and those specializing on ENDS.\(^ {109}\)

If the provisions in these observably PMI-drafted bills are carried and become part of the laws, the tobacco industry will be able to advertise IQOS and similar products to have safer or reduced health risks benefits in the Philippines. This is despite the recent declaration of U.S. FDA rejecting PMI’s claim that IQOS cuts the risks of tobacco-related diseases and its claim that IQOS is less risky than continuing cigarettes.\(^ {110}\)

General Themes during Legislative Public Sessions

The positions of the ENDS industry in their supported bills have been widely re-echoed during committee hearings in Congress. Notably, the tobacco industry, through its umbrella representative Philippine Tobacco Institute, has been observing the debates based on attendance records and third-party reports.\(^ {111}\) During their participation in both hearings of the House of Representatives and the Senate, the ENDS industry, principally through PECIA, ardently pushed for the following positions:

a. A “Balanced Policy” and “Seat at the Table” for the Industry

This “balanced policy” concept was originally applied in the Tobacco Regulation Act,\(^ {112}\) which regulates the use, sale, distribution, promotion and advertisement of tobacco products in order to promote a healthy environment and protects its citizens from the hazards of tobacco products but also ensures that the interest of the tobacco manufacturers, growers, farmers and

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106 Fuma! describes itself as the “Philippines #1” smoking shops and sells cigarettes, cigars, rolling papers, pipes, tobacco, lighters, grinders, vape, and smoking accessories. See fuma.ph.
109 Planet Vape homepage: http://planetvape.ph/.
111 The Philippine Tobacco Institute (PTI) is an incorporated association of tobacco manufacturers and retailers in the Philippines, representing substantially all the local cigarette market share. Its members include: Association Anglo American Tobacco Corporation; Fortune Tobacco Corporation; GB Global Exprez, Inc.; GB-BEM Cigarette Company, Inc.; La Suerte Cigar & Cigarette Factory; JTI Philippines, Inc.; JTI Asia Manufacturing Corp.; Philip Morris Manufacturing Inc.; and PMFTC Inc. (Philip Morris Fortune Tobacco Corporation). PTI represents the tobacco industry in the IAC-T)as a voting member.
112 “[T]he government shall institute a balanced policy whereby the use, sale, and advertisements of tobacco products shall be regulated in order to promote a healthful environment and protect the citizens from the hazards of tobacco smoke, and at the same time ensure that the interest of tobacco farmers, growers, workers and stakeholders are not adversely compromised.” R.A. 9211, §2.
stakeholders are not adversely compromised. The so-called “balanced policy” resulted to the highest form of tobacco industry interference in the Philippines, as the tobacco industry was made a member of the Inter-Agency Committee–Tobacco, the body that exclusively implements RA 9211, together with pro-tobacco agencies, NTA, and the Department of Agriculture.\textsuperscript{113} HB 532, which proposes the amendment of RA 9211 to include “electronic smoking devices” restates this purported balanced policy.

b. Regulation by the DTI instead of DOH

During the hearings conducted before the House of Representatives on 13 March 2018 for these bills, a principal author of HB 532 openly called the attention of the FDA in classifying ENDS products as health devices. He claimed that FDA does not even regulate tobacco products; hence, it cannot regulate ENDS.\textsuperscript{114} The discussion, then, shifted to the authority of the FDA to regulate the products, with some HOR members expressing that it should be the DTI that should regulate the products under its Bureau of Product Standards.

c. E-cigarettes as a Harm Reduction Strategy

Although there are numerous studies showing the various risks and harms connected with e-cigarette use, ENDS lobby groups have widely promoted the tobacco industry-friendly concept of “harm reduction.” In the HOR, HB 3330 and 7289 state a “duty of the State” to promote harm reduction measures by encouraging the availability of e-cigarette products. This position—on the relative safety of ENDS products as against conventional tobacco products—was reiterated in the Senate deliberation of SB 1538.

Moreover, HOR members have supported a House Resolution advocating for such position.\textsuperscript{115} On May 8, 2017, Representatives Anthony Bravo and Jose Tejada endorsed to the Joint Committee on Health and Trade and Industry of the House of Representatives, House Resolution No. 973. It urges the DOH to adopt in its National Tobacco Control Strategy (NTCS), the use of e-cigarettes as one of its harm reduction measures.

On May 16, 2018, HR 973 was adopted via substitution with and through HR 1885 and endorsed by medical professionals in the House of Representatives. HR 1885 is the latest proposed Resolution respecting

\textsuperscript{113} R.A. 9211, §29. Currently, the tobacco industry is represented by the Philippine Tobacco Institute, Inc. an association of local and transnational tobacco manufacturers, distributors, and retailers, which has legally challenged several tobacco control policies in the Philippines. Its members include: Association Anglo American Tobacco Corporation, Fortune Tobacco Corporation, GB Global Exprez, Inc., GB-BEM Cigarette Company, Inc., La Suerte Cigar & Cigarette Factory, JTI Philippines, Inc., JTI Asia Manufacturing Corp., Philip Morris Manufacturing, Inc., and PMFTC, Inc.

\textsuperscript{114} Due to a legal challenge by the Philippine Tobacco Institute, the agency was enjoined by the court from regulating tobacco products and the case (Department of Health v. Philippine Tobacco Institute, G.R. No. 200431) is pending before the Supreme Court of the Philippines.

\textsuperscript{115} The DOH has responded to this House Resolution in a press release dated 25 August 2018. It stated: “A series of long-term epidemiological and peer-reviewed studies are required to conclude that e-cigarettes are less harmful than conventional smoking. Contrary to the claim regarding the effectiveness of e-cigarette as a smoking cessation aid, there is barely any evidence based researches to prove so. The lack of conclusive data regarding the long-term effects of using e-cigarettes, its health risks cannot be ignored. The precautionary principle recommends that, until conclusive data regarding their safety have been established, regulatory measures should aim at reducing exposure to these products.”
e-cigarettes in the Philippines. The Resolution cited alleged merits of e-cigarette use in reducing smoking in other countries such as the United Kingdom. In its Facebook page, the PECIA announced, welcomed, and hailed the resolution. PECIA was also quoted as saying: “The ‘Bravo resolution’ is an important first step in convincing the DOH to consider e-cigarettes as an additional resource in the country’s [NTCS]. PECIA stands behind Rep. Anthony Bravo in urging the DOH to review the numerous independent international studies that show e-cigarettes are a less harmful alternative to conventional cigarettes and are viable smoking cessation aids.” This position was widely lauded across ENDS circles.

The DOH responded to this House Resolution in a 25 August 2018 press statement, saying “[s]ince 2014, the DOH has issued Administrative Order (AO) No. 2014-008 on the regulation of e-cigarettes which are classified as combination drugs and medical devices, and not tobacco products or conventional cigarettes. Any health product, to be authorized by the FDA to be made available in the market, need to follow the requirements for ingredient listing, reporting of harmful and potentially harmful constituents, and submission of health research documents if there would be claims for their use as smoking cessation aides.”

2. Participation in Local Legislative Development

Issues in national-level regulation have prompted several LGUs in regulating the use, sale, or purchase of ENDS products within their jurisdictions by passing ordinances. This stems from local governments’ authority to enact public welfare ordinances not contrary to national laws and “[w]ide discretion is vested on the legislative authority to determine not only what the interests of the public require but also what measures are necessary for the protection of such interests.” Balanga City, for instance, has effectively denied business permits of ENDS retailers for sale and distribution as of 2016 on the basis of its own ordinance.

Because of this initiative from LGUs, the

116 See https://web.facebook.com/PECIA/?_rdr=1&_rdr.
120 “Every local government unit shall exercise the powers expressly granted, those necessarily implied therefrom, as well as powers necessary, appropriate, or incidental for its efficient and effective governance, and those which are essential to the promotion of the general welfare. Within their respective territorial jurisdictions, local government units shall ensure and support, among other things, … promote health and safety, enhance the right of the people to a balanced ecology, … and preserve the comfort and convenience of their inhabitants.” Local Government Code, art. 16.
122 According to the City Licensing and Franchising Office.
123 Balanga City Ordinance No. 16, series of 2016 (Tobacco Free Generation End Game Strategy Ordinance of Balanga City, Bataan).
ENDS industry has also actively sought participation in local legislative councils where ENDS regulation is concerned. Two case studies are described here, which involve Baguio City and Quezon City, respectively. They demonstrate the various activities that the industry employs to preempt local industry-friendly regulation.

Case Study: The City of Baguio Challenge to Ordinance No. 34, series of 2017

One of the important amendments to the City’s anti-smoking ordinance is the inclusion of ENDS. Under the amended ordinance, some of the prohibited acts included: a) vaping in enclosed or partially enclosed public places, workplaces, public conveyances, whether mobile or stationary, or other public places, except in designated smoking or vaping areas duly approved and fully compliant with the requirements of the ordinance; b) vaping in schools and other places frequented by minors; and c) selling and distribution of e-cigarettes within 100 meters from schools, playgrounds, and other places frequented by minors, as well as the open display of the products in points of sale establishments.

This inclusion was opposed by more than 50 owners and retailers of vaping shops (petitioners) in Baguio City. Through a letter addressed to the City Mayor of Baguio City, they claimed that e-cigarettes should be treated differently from tobacco products for the reason that their products are “safer alternatives” to tobacco products. They insisted that there should be a separate ordinance regulating their products.

During the hearing for the Petition held by the City Council on March 5, 2018, the petitioners were represented by PECIA. PECIA asked the City Council to re-consider and exempt them from the 100-meter access restriction against the sale and distribution of their products from schools, playgrounds, and other places frequented by minors. PECIA declared that the petitioners were part of its organization, that they self-regulate themselves, and they do not sell to minors. PECIA emphasized that vaping is the most effective way for smokers to quit their habit. They explained that since most smokers shift to e-cigarettes to quit smoking, forcing them to be in same designated area for smokers would defeat the purpose and neutralize the positive effects of vaping.

Previously, the petitioners also requested the City Council to allow them to have vape testing and vaping inside their stores in accordance with standard ventilation devices. The proposed amendment is awaiting the resolution of the City Council, but the Office of Councilor Joel A. Alangsab, the proponent of the Ordinance sought counsel from the FDA. In an undated legal opinion, the FDA acknowledged the authority of the City under the Local Government Code (LGC) to regulate
ENDS, viz:

The FDA as a regulatory body, in accordance with its mandate can require licenses from establishments and covered products prior to engaging in the manufacture, importation, exportation, sale, offer for sale, distribution, transfer and where applicable the use, testing, promotion, advertisement and/or sponsorship of health products.

Therefore, the regulatory capture and control being done by the FDA against erring establishments and products in accordance with its mandate of ensuring the safety of health products is different from the authority granted by the [Local Government Code (LGC)] to the LGUs.

The LGC has granted the LGUs autonomous power to enact ordinances they deem fit to promote the general welfare of their constituents within their territorial jurisdiction. The LGU’s authority is not dependent on other government agencies or institutions. Much less these other government agencies, like the FDA, only complements the authority of such LGUs.

In essence, the City of Baguio need not rely solely on the rules regulations issued by the DOH and/or the FDA. The City on its own accord, may ban or prohibit the sale of vape products, provided that the necessary requirements for a valid ordinance are met. Incidental to this authority granted to the LGUs, they may also confiscate and/or close erring shops or establishments not on the basis of the issuances of the DOH and/or FDA, but by virtue of such ordinance and the LGC.

The City has specifically responded to the fact that e-cigarettes sellers and retailers have established “vaping establishments,” which target the young. During the hearing on March 6, 2018 for the sought amendment, one of the Barangay Chairpersons narrated how in one instance, she confronted a nine-year-old, whom she noticed to be holding a vape device.

When asked where the device came from, the child said that the device came from a vape shop. Consequently, despite the legal threats of the ENDS industry, the City of Baguio maintained its position that its mandate is to protect the health of its population from the potential hazards of e-cigarettes and to protect the youth from any form of addiction.

Case Study: Quezon City
Passing of Ordinance No. SP-2737, series of 2018

On February 1, 2017, the Quezon City Council, proposed an ordinance,127 which sought to regulate e-cigarettes as harm reduction measures, using as support studies of the Royal College of Physicians, Public Health England, and the Lung Foundation of England—a claim consistent with PECIA positions.128 The Ordinance also expressed a “right” of smokers to be given the right

127 An Ordinance for the Regulation of E-Cigarettes in Public Places, including Public Conveyances, Advertisement and Promotions of E-Cigarettes, and Providing Penalties Therefor (filed Feb 1, 2017).
128 See PECIA Facebook post of 7 February 2017, citing alleged findings of the Royal College of Physicians and Public Health England. Compare
to choose less harmful alternatives to cigarettes. Significantly, it spoke of a “balanced policy” where both public health and the right to trade of e-cigarette manufacturers are protected.

Hence, the ordinance recommended the regulation of the use of e-cigarettes in public places, the regulation of advertising, promotion and sponsorship of e-cigarettes and the access restriction to minors. The ordinance was proposed shortly after the Vapers Summit mentioned, where the City Administrator of Quezon City proudly gave an overview of the city government’s proposed regulation on e-cigarettes. During the first hearings for this Ordinance held on 30 November 2017 and 6 June 2018, PECIA, represented by its corporate officers, openly encouraged and supported the passage of the ordinance.

This proposal has been recently approved as Ordinance No. SP-2737, series of 2018. It sets a very loose set of restrictions against ENDS, including the permission of ENDS use “[i]n all ... enclosed places that are open to the general public [and] private workplaces” except places of worship, government offices, and educational and recreational facilities primarily intended for minors. The owner or proprietor of such place merely needs to put a sign in ingress points that ENDS use is allowed. Furthermore, the Ordinance broadly allows ENDS advertising in “points-of-sale, through direct marketing, and on the internet.”

with Quezon City Ordinance No. SP-2737, s. 2018, whereas ¶3 (citing “the 2016 report of the Royal College of Physicians of the United Kingdom” and “[g]roups such as Public Health England and the British Lung Foundation.”

129 Quezon City Ordinance No. SP-2737, s. 2018, whereas ¶4 (“to fully protect the health and welfare of the citizens of Quezon City and at the same time safeguard the interests of all stakeholders, including smokers who have the right to choose less harmful alternatives to cigarettes”).

130 See https://www.facebook.com/PECIAI/posts/936788929701723.

131 §5.
**Table 5** and **Table 6** present a comparative analysis of this ordinance, together with ENDS regulation bills supported by the ENDS industry. It shows that the terminologies used in defining ENDS are the same, as well as the access restrictions they put in place, the list of prohibitions in terms of where ENDS can be used, and advertisement restrictions.

**Table 5.** Similarities in Nomenclature and General Positions between the Quezon City Ordinance and ENDS Industry-Supported Bills

<table>
<thead>
<tr>
<th>Quezon City Ordinance No. SP-2737, s. 2018</th>
<th>Bills filed before the House of Representatives</th>
<th>Bill filed before the Senate</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Title</strong></td>
<td>HB No. 3330</td>
<td>An Act Regulating the Trade of Vaporized Nicotine Products</td>
</tr>
<tr>
<td>An Ordinance for the Regulation of E-Cigarettes in Public Places, Including Public Conveyances, Advertisements and Promotions of E-Cigarettes, and Providing Penalties Therefor</td>
<td>HB No. 7289</td>
<td>An Act Regulating the Use, Sale, Packaging, Distribution, and Advertisements of Vaporized Nicotine Products</td>
</tr>
<tr>
<td><strong>Positions Taken</strong></td>
<td></td>
<td>An Act Regulating the Trade of Vaporized Nicotine Products, Particularly, the Use, Sale, Packaging, Distribution, and Communications Thereof</td>
</tr>
<tr>
<td>ENDS “should be differentiated in terms of regulation from conventional cigarettes as studies have consistently concluded that e-cigarettes are significantly safer than conventional tobacco smoking.”</td>
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<tr>
<td><strong>Nomenclature for ENDS</strong></td>
<td>Electronic cigarette or e-cigarette</td>
<td>Vaporized nicotine product</td>
</tr>
</tbody>
</table>
Table 6. Similarities in Regulatory Provisions between the Quezon City Ordinance and ENDS Industry-Supported Bills

<table>
<thead>
<tr>
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</thead>
<tbody>
<tr>
<td>Definition of ENDS</td>
<td>&quot;[M]eans any product that generates a nicotine-containing aerosol without combustion, with or without electronics or tobacco, or any component of that product, this includes but not limited to a cartridge, a tank, and a device without a cartridge or tank.&quot; (§1a)</td>
<td></td>
</tr>
<tr>
<td>Public Place Use</td>
<td>&quot;Use of [ENDS] indoors is prohibited in places of worship, hospitals or other healthcare centers, public conveyances, government offices, and educational or recreational facilities primarily intended for minors.&quot; &quot;In all other enclosed places that are open to the general public, private workplaces and those places not covered in the preceding enumeration, [ENDS] 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 such places: &quot;USE OF [ENDS] IS ALLOWED INSIDE.&quot;</td>
<td></td>
</tr>
<tr>
<td>ENDS Advertisement</td>
<td>Advertisements &quot;shall be allowed&quot; in points-of-sale, through direct marketing, and on the internet.</td>
<td></td>
</tr>
</tbody>
</table>

3. Intimidations and Harassment

Another form of ENDS industry interference that has been observed is intimidation and harassment, which were methodologically, rapidly, and massively carried out against proponents of strict regulation. This is best exemplified by the incidents after the seventh Conference of Parties (COP7) to the WHO FCTC in New Delhi, India last November 7-12, 2016.

During the event, the Civil Service Commission (CSC) Chair served as the head of the Philippine delegation to the COP7 and expressed support for the language being deliberated on the floor regarding ENDS “banning or regulation,” which was based on a WHO-prepared study. As reported by another official of the CSC, the Philippines’ position on e-cigarette was prepared and agreed upon by the members of the delegation beforehand as “the expectation for each delegate

133 "The Conference of Parties... Recognizing that some Parties have adopted various regulatory strategies with respect to ENDS/ENNDS, such as an outright ban on their manufacturing, importation, distribution and sale, the adoption of regulation similar to that applicable to medicines, their control as tobacco products, or their control as consumer products with tobacco control-like measures, while other Parties have adopted no control at all, ... invites Parties to consider applying regulatory measures such as those referred to in document FCTC/COP/7/11 to prohibit or restrict the manufacture, importation, distribution, presentation, sale and use of ENDS/ENNDS, as appropriate to their national laws and public health objectives." See Electronic nicotine delivery systems and electronic non-nicotine delivery systems (FCTC/COP/7/9) drafted at the Fifth plenary meeting (12 November 2016), in Report of the seventh session of the Conference of the Parties to the WHO Framework Convention on Tobacco Control, Delhi, India, 7–12 November 2016, at pp. 70-71, http://www.who.int/fctc/cop/cop7/FINAL_COP7REPORT_EN.pdf.

134 Interview conducted on 18 July 2018 (identity withheld upon request).
[was] to come up with one position paper for every issue that would surface during the COP7 and one of the issues that was placed in the agenda was about the e-cigarettes or ENDS.” Moreover, it was reported that despite a different position taken by DTI, the Chair adopted the position of the delegation by preponderance and “pursued the original position of the team.”

A few days after the Conference, TVP attacked the CSC Chair through press releases in major newspapers in the country. TVP questioned the authority of the CSC to take and express the country’s position, contending that health is not a mandate of the CSC and that the CSC went beyond its authority.135

Clarifying the issue, the CSC and the DOH, thereafter, issued a joint statement.136 CSC has been at the forefront of the government’s tobacco control agenda being the head of the National Tobacco Control Committee on Article 5.3 (NTCC 5.3), which is the steering committee of FCTC Article 5.3. The said article ensures the proper creation and implementation of tobacco control laws and policies, which should be in compliance with the FCTC.

In addition, CSC is implementing CSC issued Memorandum Circular No. 17 s. 2009 (Smoking Prohibition Based on 100% Smoke-free Environment Policy.) which establishes smoke-free environment in work places in the public sector.

It was also explained that Philippines’ statement during the COP were agreed upon by the members of the Philippine Delegation and cleared by Secretary of Health.

Civil society organizations are also not exempted from the industry’s harassment and intimidation. When HealthJustice Philippines, posted in its Facebook page137 its recommendation to the President to ban e-cigarettes, the post prompted outrage from pro-e-cigarettes and vaping campaigners and/or users.

The posts generated more than 600 comments, most of which are offensive and derogatory against the proponent. Some of these online remarks cited the position of PECIA. A coordinated attack against the organization was also instigated by industry lobbyists as a response to the post.

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137 See: https://web.facebook.com/HealthJustice/.
Through a comprehensive analysis of ENDS and tobacco industry interference in policy setting, triangulating mixed methodologies and data sources, this study shows that the tobacco industry, while discreet in terms of lobbying representation, has been a major actor for influencing policy formulation for ENDS in the Philippines.

Of the nine (9) bills proposing ENDS regulation in Congress, six (6) are oriented to adopting ENDS industry positions, demonstrating industry origin or draftsmanship. More importantly, three (3) bills—two at the House of Representatives and one in the Senate—show the involvement of Philip Morris International, likely through PMFTC. In particular, these bills seek to pre-empt the regulation of heated tobacco products and the approval of their reduced risk health claims by regulatory bodies. This is the first observation globally of this unique strategy of tobacco industry interference.

The legislative agenda of the ENDS industry to exclude HTPs from the existing regulatory frameworks of the Tobacco Regulations Act, Graphic Health Warnings Law, excise taxes, and other national and local policies promotes the interest to the industry by providing a non-restrictive regulation when IQOS and similar HTPs are formally introduced.

All told, this study affirms that ENDS industry interference must be covered by Article 5.3-based prohibitions. The unity of interest between the ENDS industry and the tobacco industry is unmistakable. The intersected and inseparable goals of the ENDS industry and the tobacco industry in the Philippine ENDS market warrants the extension of ENDS industry interference as a form of tobacco industry interference proscribed by Article 5.3 of the WHO FCTC and covered by existing administrative issuances on the subject, such as the CSC-DOH JMC 2010-01. This treatment is also in recognition of the vested commercial interests of both industries, which are antithetical to the demands of the broadest public health protection.

To this end, all bills that have ENDS and tobacco industry draftsmanship should be unequivocally rejected. Strategic multi-sectoral support and cooperation must be pursued to ensure that accountability is raised before members of the national legislature, who are deliberating on the issue at various levels (i.e., committee and

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138 Other issuances include: Department of Science and Technology Memorandum dated 24 May 2010 (Commitment to the World Health Organization Framework Convention on Tobacco Control); Department of Education Order No. 6, series of 2012 (Guidelines on the Adoption and Implementation of Public Health Policies on Tobacco Control and Protection Against Tobacco Industry Interference); Bureau of Internal Revenue Memorandum Order No. 16-2012 (Smoking Prohibition based on 100% Smoke-Free Environment Policy, Restrictions on Interactions with the Tobacco Industry and Imposition of Sanctions for Violation of the Rule).
plenary). Moreover, both industries, including their industry lobbyists and agents, must be removed from participation in legislative formulation, consistent with Article 5.3 of the FCTC.

The protection, respect, and fulfillment of the right to health of the Filipino people demand that ENDS policy formulation must be free from the historically documented racketeering of the tobacco industry.
HealthJustice Philippines is a leading think tank in public health policy development and reform in the Philippines, with specialization in tobacco control and health promotion. Its technical, research, and legal expertise have been instrumental in the design and formation of various national legislations such as the Sin Tax Reform Act of 2012 and the Graphic Health Warnings Act of 2014, as well as executive orders, administrative issuances, and local government ordinances in important facets of public health. Its team of public health, legal, economics, and governance experts continues to work together with partners and fellow advocates in government, the civil society, and the private sector towards the full and strong implementation of the WHO FCTC in the country. HealthJustice is also the Philippine program member of the global NCD Alliance and, recently, a CSO with consultative status accredited by the United Nations Economic and Social Council for the United Nations High-Level Meeting on NCDs. In 2012, it received the Bloomberg Philanthropies Award for Global Tobacco Control.