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Food and Drug Administration
Civic Drive, Filinvest Corporate City
Alabang, Muntinlupa City
Philippines

Re: FDA draft General Guidelines for the Regulation of Vapor Products and Heated Tobacco Products

June 5, 2020

Dear Director General Domingo:

We appreciate the opportunity to submit comments regarding the FDA draft General Guidelines for the Regulation of Vapor Products and Heated Tobacco Products. However, rather than investigating only the public health threats of e-cigarettes and heated tobacco products, we suggest the committees also consider the public health opportunities of these products. Smoking is the leading cause of preventable death globally, and it is vital that we continually evaluate our strategies for decreasing tobacco-related morbidity and mortality. E-cigarettes provide such a strategy.

We believe these products present a public health opportunity to improve the lives of people who use combustible products and cannot or do not want to stop.

With this in mind, we write to urge the Food and Drug Administration to consider pragmatic regulations that allow Filipino citizens broad access to reduced-risk products. In light of new scientific and policy evidence¹ that has emerged over the last five years supporting a global harm reduction approach to smoking, we strongly feel that appropriate regulation of new products will advance the objective of protecting and improving public health.

ENDS are a Harm Reduction and Smoking Cessation Tool

¹ Carrie Wade and Chelsea Boyd, "Tobacco Harm Reduction: Evidence Update," *R Street Policy Study* No. 179, August 2019.

<https://www.rstreet.org/2019/08/07/tobacco-harm-reduction-evidence-update/>

The Royal College of Physicians²; Public Health England³; the National Academies of Science, Engineering and Medicine⁴; and the FDA⁵ have recognized that nicotine products exist on a continuum of risk, with e-cigarettes and heated tobacco product technologies at the lower end near traditional nicotine replacement therapies, and combustible cigarettes at the highest end of the risk spectrum. Importantly, in its comprehensive report, the Royal College of Physicians stated that e-cigarettes are unlikely to exceed 5 percent of the risk associated with combustible cigarettes.⁶ These products are recognized as presenting a reduced risk because they don't employ the traditional cigarette combustion process that releases 7,000 chemicals—some of which are highly carcinogenic. Former FDA commissioner Scott Gottlieb has made reduced-risk products like e-cigarettes central to the FDA's roadmap:

While it's the addiction to nicotine that keeps people smoking, it's primarily the combustion, which releases thousands of harmful constituents into the body at dangerous levels, that kills people. This fact represents both the biggest challenge to curtailing cigarette addiction—and also holds the seeds of an opportunity that's a central construct for our actions. E-cigarettes may present an important opportunity for adult smokers to transition off combustible tobacco products.⁷

In the spirit of this strategy, the first heated tobacco product, IQOS, was granted marketing approval by the FDA on April 30, 2019.⁸ The FDA would not have granted this heated tobacco product marketing approval if it did not meet the rigorous standards set forth by the Premarket Tobacco Authorization (PMTA) program, which includes being evaluated by the FDA as “appropriate for the protection of public health,” taking into account the risks and benefits to the population as a whole:

² Tobacco Advisory Group, *Nicotine without smoke: Tobacco harm reduction*, Royal College of Physicians, April 28, 2016, pp. 87. <https://www.rcplondon.ac.uk/projects/outputs/nicotine-without-smoke-tobacco-harm-reduction-0>.

³ Ann McNeill, et al., “E-cigarettes: a new foundation for evidence-based policy and practice” Health & Wellbeing Directorate, Public Health England, August 2015. https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/454517/E-cigarettes_a_firm_foundation_for_evidence_based_policy_and_practice.pdf

⁴ “The Public Health Consequences of E-cigarettes,” National Academies of Science, Engineering and Medicine, January 2018. <http://nationalacademies.org/hmd/reports/2018/public-health-consequences-of-e-cigarettes.aspx>. “Across a range of studies and outcomes, e-cigarettes appear to pose less risk to an individual than combustible tobacco cigarettes.”

⁵ Scott Gottlieb, M.D., on comprehensive regulatory plan to shift trajectory of tobacco-related disease, death, “Statement from FDA Commissioner,” U.S. Food and Drug Administration, July 27, 2017. <https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm568923.htm> “A key piece of the FDA's approach is demonstrating a greater awareness that nicotine—while highly addictive—is delivered through products that represent a continuum of risk and is most harmful when delivered through smoke particles in combustible cigarettes.”

⁶ Tobacco Advisory Group, *Nicotine without smoke: tobacco harm reduction*, Royal College of Physicians, April 28, 2016, p. 87. <https://www.rcplondon.ac.uk/projects/outputs/nicotine-without-smoke-tobacco-harm-reduction-0>.

⁷ Scott Gottlieb, M.D., on new steps to address epidemic of youth e-cigarette use, “Statement from FDA Commissioner,” U.S. Food and Drug Administration, Sept. 11, 2018. <https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm620185.htm>

⁸ FDA permits sale of IQOS Tobacco Heating System through premarket tobacco product application pathway, April 30, 2019. <https://www.fda.gov/news-events/press-announcements/fda-permits-sale-iqos-tobacco-heating-system-through-premarket-tobacco-product-application-pathway>

The statute provides that the basis for this finding shall be determined:
with respect to the risks and benefits to the population as a whole, including users and nonusers of the tobacco product, and taking into account –

(A) the increased or decreased likelihood that existing users of tobacco products will stop using such products; and

(B) the increased or decreased likelihood that those who do not use tobacco products will start using such products.⁹

Although there are a number of pharmaceutical products that can help smokers quit, their low success rates and lack of appeal to smokers necessitate that the public health community consider expanding the armamentarium to include ENDS. It is important to remember that it's not only nicotine dependence that makes quitting combustible cigarettes difficult. For some, smoking offers stress relief, comradery and other psycho-social pleasure, and some even consider the habit a component of their identity. This often makes the physical act of smoking just as difficult to quit as the nicotine smoking provides. These are additional reasons why the availability of ENDS products has successfully driven down rates of combustible use in countries that have embraced these technologies as part of their tobacco control framework.

Indeed, ENDS have quickly become the number one quit-smoking tool in many parts of the world, allowing an untold number of smokers to quit cigarettes. Public health modeling has suggested that e-cigarettes are contributing to more rapid declines in smoking rates than were seen in previous years.¹⁰ In the United States and United Kingdom e-cigarettes have outpaced traditional quit methods (varenicline, nicotine replacement therapies and counseling)¹¹ and demonstrate a higher degree of success.¹² Furthermore, in a randomized trial, smokers who used e-cigarettes as a cessation device achieved sustained abstinence at roughly twice the rate of smokers who used nicotine replacement therapy.¹³

Heated tobacco products have contributed to a dramatic decline in cigarette consumption in Japan, where cigarette sales volumes have fallen by 33 percent in three years; from 43.6 billion sticks in

⁹ U.S. Department of Health and Human Services Food and Drug Administration Section 910 of the Federal Food, Drug, and Cosmetic Act - Application for Review of Certain Tobacco Products. Sec 910(c)(4).

¹⁰ David T. Levy et al., "Examining the relationship of vaping to smoking initiation among US youth and young adults: a reality check," *Tobacco Control* (2018). <https://www.ncbi.nlm.nih.gov/pubmed/30459182>.

¹¹ Ann McNeill, et al., "E-cigarettes: a new foundation for evidence-based policy and practice" Health & Wellbeing Directorate, Public Health England, August 2015. https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/454517/E-cigarettes_a_firm_foundation_for_evidence_based_policy_and_practice.pdf

¹² S. H. Zhu, et al., "E-cigarette use and associated changes in population smoking cessation: evidence from US current population surveys," *BMJ* 358, j3262 (2017). <https://www.bmj.com/content/358/bmj.j3262>

¹³ Peter Hajek et al., "A Randomized Trial of E-Cigarettes versus Nicotine-Replacement Therapy," *The New England Journal of Medicine* 380 (2019), pp. 629-37.

January-March 2016 to 29.1 billion sticks in January-March 2019.¹⁴ Analysts at Citi Group attribute this disruption of the cigarette market to heated tobacco products.¹⁵

Countries that have adopted approaches where these products are regulated and favored over combustible products have seen dramatic decreases in smoking rates.

Global Regulation of ENDS

Above all, we believe that:

- 1) Regulations should be ‘risk-proportionate’—meaning that tougher measures should be applied to the most risky products (cigarettes) and a more permissive approach should be taken with lower-risk products, with the aim of encouraging users to switch from high-risk to low-risk products.
- 2) A well-defined regulatory environment is necessary for consumer goods that carry some risk but can also mitigate chemical, electrical, thermal and mechanical risks to users and discourage uptake by adolescents.
- 3) Creating an environment that allows for responsible use of ENDS is preferable to an environment where black markets, adulterated products and criminalization flourish.

When considering regulations to reduce the burden of smoking, we strongly urge the FDA to consider the utility of harm reduction and reduced-risk products alongside other tobacco control measures. We firmly believe that harm reduction is complementary to established tobacco control measures and not an alternative. We recommend that these products be subject to policy and regulatory measures that maintain the safety of these products and increase their availability with the goal of displacing combustible cigarettes. This can only be done through a multifaceted approach that addresses product standards, evolving technology and taxation structures that incentivize people to move away from more harmful products.

This view is widely held among tobacco policy experts. In October 2018, 72 experts wrote the director general of the WHO calling for the adoption of a progressive approach to tobacco harm reduction to achieve our common aims: to reduce the burden of cancer, cardiovascular and respiratory disease in support of the Sustainable Development Goals:

ENDS include established and new technologies that deliver nicotine to the user without combustion of tobacco leaf and inhalation of tobacco smoke. These technologies offer the prospect of significant and rapid public health gains through ‘tobacco harm reduction’. Users who cannot or choose not to quit using nicotine have the option to switch from the highest risk products (primarily cigarettes) to products that are, beyond reasonable doubt, much lower risk than smoking products (e.g., pure nicotine products, low-toxicity smokeless tobacco

¹⁴ “Japanese Domestic Cigarette Sales Results, Monthly reports 2016-19,” *Japan Tobacco*, June 2019.
<https://www.jt.com/media/news>.

Cummings KM, Nahhas GJ, Sweanor DT. What Is Accounting for the Rapid Decline in Cigarette Sales in Japan? *Int J Environ Res Public Health*. 2020 May 20;17(10):3570.

¹⁵ Adam Spielman, “The new world of tobacco,” Citi Group, April 18, 2018, p. 20.
<https://thefly.com/landingPageNews.php?id=2691422&headline=PM;BTI-Citi-upgrades-Philip-Morris-downgrades-BTI-in-new-world-of-Tobacco>.

products, vaping or heated tobacco products). We believe this strategy could make a substantial contribution to the Sustainable Development Goal to reduce premature deaths through non-communicable diseases (SDG Target 3.4).¹⁶

While the World Health Organization's Conference of the Parties (CoP) has issued a statement indicating that a ban of these products may be advisable in some situations, most party members have instead taken the approach to regulate these products, which is also a recommendation of the CoP.¹⁷ This approach protects the populace from illegal and adulterated products and also does not create an environment where very dangerous products, such as combustible cigarettes, are given favor.

Furthermore, it is predicted that proper regulation of tobacco products, including regulation of ENDS, predicts decreased cigarette and e-cigarette use and increased quality-adjusted life years over time.¹⁸ In applying various forms of regulatory approaches including public health campaigns, taxation and e-cigarette availability, Doan et al. demonstrated that a combination of these approaches will decrease cigarette and e-cigarette consumption by approximately 5 to 10 percent by 2060. Left alone, smoking rates will continue to stagnate, and combustible products will continue to kill millions each year.

Regulatory Recommendations

Minimum Purchasing Age

Adult smokers are not the only population impacted by e-cigarettes, and it is important to address youth use of both e-cigarettes and combustible cigarettes.

Preventing non-smoking young people from establishing both e-cigarette and combustible cigarette use is vital to the future health of the population. Although the rate of past-30-day e-cigarette use among young people has increased in the United States, the smoking rate has continued to decline since e-cigarettes were introduced.¹⁹ This suggests that young people who try e-cigarettes are not transitioning to combustible cigarettes in large numbers. This is supported by Levy et al.'s study that analyzed data from the major national surveys of youth tobacco use and found evidence that the rate of decline in combustible cigarette use began declining more quickly after the introduction of e-cigarettes. Furthermore, it is well-established that young people who use or try e-cigarettes are likely to have a history with other tobacco use. Raising the age of purchase—like the Philippines did recently—and enforcing this regulation, will have positive impacts on smoking rates in future generations.

¹⁶ Letter from 72 specialists in nicotine science, policy and practice to Director General World Health Organisation, *Innovation in tobacco control: developing the FCTC to embrace tobacco harm reduction*, 1 October 2018 <https://clivebates.com/documents/WHOCOP8LetterOctober2018.pdf>

¹⁷ "Progress report on regulatory and market developments on electronic nicotine delivery systems (ENDS) and electronic non-nicotine delivery systems (ENNDS)," Conference of the Parties to the WHO Framework Convention on Tobacco Control, June 2018, pp. 4. https://www.who.int/fctc/cop/sessions/cop8/FCTC_COP_8_10-EN.pdf

¹⁸ Thi Thanh Tra Doan et al., "Evaluating smoking control policies in the e-cigarette era: a modelling study," *Tobacco Control* Published Online First: 04 September 2019. <https://tobaccocontrol.bmj.com/content/early/2019/09/03/tobaccocontrol-2019-054951>

¹⁹ David T. Levy et al., "Examining the relationship of vaping to smoking initiation among US youth and young adults: a reality check," *Tobacco Control* (2018). <https://www.ncbi.nlm.nih.gov/pubmed/30459182>.

Mathematical modeling studies and real-world data from areas with available data indicate that raising the age of purchase to 21 will result in a highly significant decrease in youth use of combustible tobacco products and ENDS in a relatively short period.²⁰

This intervention is predicted to have larger effects on initiation of tobacco products for adolescents aged 15-18 than other interventions, such as increasing taxes, and will have a greater and faster impact on long-term smoking rates among youth.²¹ Following implementation of a 21-to-purchase law in Needham, Massachusetts, there was a 47 percent reduction (from 13 to 7 percent) in past-30-day smoking rates (past-30-days use) among high schoolers over four years (2008-2012).²²

Advertising, Packaging and Health Warnings

Advertising is important to innovative entrants in reaching the established pool of smokers and in diverting would-be smokers away from cigarettes. Bans on advertising protect the dominant market incumbents, in this case the cigarette trade of the major tobacco companies. We do not think it is wise for a government to protect the tobacco industry in this way. We believe that public health will benefit by allowing more effective methods of public communication that are specifically targeted to combustible cigarette users with a duty to advertise responsibly and avoid placement and themes that appeal disproportionately to youth.

While standardized packaging removes the potential for marketing to influence never-smokers to initiate combustible use, banning pack inserts eliminates a method of marketing directly to smokers. Since few people other than current smokers are likely to purchase combustible cigarettes and open the packaging, pack inserts are a low-risk means of communicating health information to smokers.

A 2018 study of young adults in the United Kingdom found that 60 percent of those surveyed thought that pack inserts were a good way to provide information about quitting.²³ A similar study with adult smokers also concluded that pack inserts with health information were an effective communications tool for reaching current smokers.²⁴ This study indicates that pack inserts are an opportunity to provide smoking cessation tips and benefits to current smokers.

Pack inserts that communicate health information are not without precedent. The Canadian government and the EU require inserts in cigarette packs that communicate the benefits of quitting and

²⁰ Sajjad Ahmada and John Billimek, "Limiting youth access to tobacco: Comparing the long-term health impacts of increasing cigarette excise taxes and raising the legal smoking age to 21 in the United States," *Health Policy* 80:3 (2007), pp. 378-91. <https://www.ncbi.nlm.nih.gov/pubmed/16698112>; Shari Kessel Schneider et al., "Community reductions in youth smoking after raising the minimum tobacco sales age to 21," *Tobacco Control* 25:3 (2015), pp. 355-59. <https://tobaccocontrol.bmj.com/content/25/3/355>.

²¹ Sajjad Ahmada and John Billimek. <https://www.ncbi.nlm.nih.gov/pubmed/16698112>.

²² Shari Kessel Schneider et al., <https://tobaccocontrol.bmj.com/content/25/3/355>.

²³ Crawford S. Moodie et al., "Perceptions of cigarette pack inserts promoting cessation and dissuasive cigarettes among young adult smokers in the UK: a cross-sectional online survey," *BMJ Open*. 8:e019662 (2018). doi: 10.1136/bmjopen-2017-019662

²⁴ Crawford S. Moodie, "Adult smokers' perceptions of cigarette pack inserts promoting cessation: a focus group study," *Tobacco Control* 27:1 (2018), pp. 72-77. <https://www.ncbi.nlm.nih.gov/pubmed/28153959>.

tips for doing so.²⁵ This method allows an inexpensive, direct and targeted marketing avenue to supplement other stop-smoking campaigns.

Several studies have evaluated the effects of relative-risk labels on tobacco products with consistent results. For example, proposed labels of Snus products describing the decreased relative risk compared with combustible cigarettes increased the likelihood and motivation to buy and try Snus among current smokers with little effect on former or never smokers.²⁶ Of particular importance is the finding that if the viewer finds the warning to be believable, they are more likely to act accordingly. This was true for all survey participants but had the most effect on current smokers.

Consistent with this study are findings that labels describing the reduced risk of Snus compared to combustible cigarettes better inform users of relative harm but have no effect on the perceptions of the addiction potential of Snus—study participants are aware of reduction in potential harms without compromising the knowledge of the addiction potential of nicotine.²⁷ When survey participants were provided a more thorough fact sheet explaining scientific knowledge of nicotine and the relative harms of smokeless tobacco versus combustible tobacco, their knowledge of both nicotine replacement therapies and smokeless tobacco versus cigarettes greatly increased, as did the likelihood that future quit attempts would be assisted by one of these products. This is significant because assisted quit attempts have higher rates of success. In fact, compared to the nicotine patch or gum, Snus users have been shown to enjoy higher rates of success in quitting combustible cigarettes.²⁸ It would be logical to expect the same results in applying these techniques to ENDS products.

Maximum nicotine limits in electronic nicotine delivery systems.

Despite the absence of any maximum nicotine limits for combustible cigarettes, there are examples of regulatory agencies employing maximum nicotine concentrations to minimize the addiction potential of ENDS. While, in theory, limiting the availability of higher nicotine strengths may be helpful in preventing future generations from establishing use of these products, we believe that this must be balanced with the need to incentivize current smokers to switch to safer products. For example, the European Union's 20 mg/ml or 2 percent nicotine maximum for alternative nicotine delivery systems has prevented more concentrated products from entering the market, which may discourage some smokers from transitioning away from combustible cigarettes.²⁹ In their article assessing nicotine absorption from e-cigarettes, Farsalinos et al. state that "Nicotine delivery to the bloodstream is important in determining

²⁵ Crawford S. Moodie, <https://www.ncbi.nlm.nih.gov/pubmed/28153959>.

Title III, Article 20(4), "Tobacco Products Directive 2014/40/EU," *Official Journal of the European Union*. April 3, 2014, pp. L127/25-L127/29.

https://ec.europa.eu/health/sites/health/files/tobacco/docs/dir_201440_en.pdf

²⁶ B. Rodu, N. Plurphanswat, J. R. Hughes, K. Fagerstrom, Associations of Proposed Relative-Risk Warning Labels for Snus With Perceptions and Behavioral Intentions Among Tobacco Users and Nonusers. *Nicotine & Tobacco Research* 18, 809-816 (2016).

²⁷ D. Mays, M. B. Moran, D. T. Levy, R. S. Niaura, "The Impact of Health Warning Labels for Swedish Snus Advertisements on Young Adults' Snus Perceptions and Behavioral Intentions," *Nicotine & Tobacco Research* 18, 1371-1375 (2016).

²⁸ K. E. Lund, A. McNeill, J. Scheffels, "The use of snus for quitting smoking compared with medicinal products," *Nicotine & Tobacco Research* 12, 817-822 (2010).

²⁹ European Commission. "E-cigarette Myth Buster."

https://ec.europa.eu/health/sites/health/files/tobacco/docs/tobacco_mythbuster_en.pdf

the addictiveness of ECs, but also their efficacy as smoking substitutes.”³⁰ They also find that e-liquids with a nicotine concentration of approximately 50 mg/ml are necessary to deliver nicotine in a similar profile to combustible cigarettes.

Since smokers are accustomed to the nicotine delivery profile of combustible cigarettes, it follows that an alternative product should be able to achieve similar effects, at least while users make their initial transition, lest combustible cigarettes maintain a competitive advantage over reduced-risk products. In fact, research indicates that higher nicotine concentrations help smokers make the initial switch from combustible cigarettes and that e-liquids with higher nicotine concentrations are better able to produce nicotine delivery patterns similar to combustible cigarettes relative to those with lower nicotine concentrations.³¹ This is one aspect of e-cigarettes that makes them an ideal cessation tool. They can achieve nicotine delivery similar to combustible cigarettes, and the concentration can be decreased gradually based on the user’s needs and desires.³²

The ability to achieve a similar nicotine delivery profile to that of combustible cigarettes is likely one reason that e-cigarettes are more effective cessation devices than pharmaceutical nicotine replacement therapy treatments.³³ During daily smoking, typical peak blood nicotine concentrations range from 19 to 50 ng/ml, while typical trough concentrations range from 10 to 37 ng/ml; depending on how the cigarette is smoked, each cigarette increases blood nicotine concentrations by 5 to 30 ng/ml.³⁴ By contrast, unrestricted use of nicotine replacement therapy products generally achieves only one to two-thirds the blood nicotine concentrations achieved from combustible cigarettes. For an individual with high nicotine dependence, the ability to more accurately duplicate the nicotine delivery profile of combustible cigarettes with e-cigarettes may be what makes their quit attempt succeed when previous attempts failed.

Farsalinos et al. found that 20 percent of e-cigarette users initiated use with e-liquids that contained nicotine concentrations greater than 20 mg/ml and nearly a quarter used nicotine concentrations greater than 20 mg/ml at the time they stopped using combustible cigarettes.³⁵ These results suggest that increasing the availability of e-liquids with nicotine concentrations greater than 20 mg/ml may assist smokers who have not quit successfully with the products currently available. Furthermore, the study indicates that nicotine concentrations used after cessation from combustible cigarettes decreased compared to what was used at initiation or complete transition.

³⁰ Konstantinos Farsalinos et al., “Nicotine absorption from electronic cigarette use: comparison between first and new-generation devices,” *Scientific Reports* 4:4133 (2014).

<https://www.ncbi.nlm.nih.gov/pubmed/24569565/>

³¹ Lynn Dawkins et al., “Self-titration by experienced e-cigarette users: blood nicotine delivery and subjective effects,” *Psychopharmacology (Berl)* 233:15-16 (2016), pp. 2933-2941.

<https://www.ncbi.nlm.nih.gov/pubmed/27235016>

³² Konstantinos Farsalinos et al., “Evaluating Nicotine Levels Selection and Patterns of Electronic Cigarette Use in a Group of ‘Vapers’ Who Had Achieved Complete Substitution of Smoking,” *Substance Abuse* 7 (2013), pp. 139-146. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3772898/>

³³ Peter Hajek et al., “A Randomized Trial of E-Cigarettes versus Nicotine-Replacement Therapy,” *The New England Journal of Medicine* 380 (2019), pp. 629-37. <https://www.nejm.org/doi/full/10.1056/NEJMoa1808779>

³⁴ Neal L. Benowitz et al., “Nicotine Chemistry, Metabolism, Kinetics and Biomarkers,” *Handbook of Experimental Pharmacology* 192 (2009), pp. 29-60. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2953858/>

³⁵ Konstantinos Farsalinos et al., “Evaluating Nicotine Levels Selection and Patterns of Electronic Cigarette Use in a Group of ‘Vapers’ Who Had Achieved Complete Substitution of Smoking,” *Substance Abuse* 7 (2013), pp. 139-146. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3772898/>

Appropriate Regulatory Pathways

E-cigarettes and heated tobacco products are not pharmaceutical products and should not be regulated as such. Treating e-cigarettes and heated tobacco products similar to pharmaceutical products will deprive 16.6 million Filipino smokers of access to less harmful alternatives. Pharmaceutical products are held to extraordinarily high standards, since they intend to treat or cure medical problems. E-cigarettes and heated tobacco products, on the other hand, offer a less harmful substitution for an unhealthy behavior.

There is compelling evidence that e-cigarettes and heated tobacco products are much less hazardous than combustible cigarettes, and it is in theory possible to treat them as therapeutic smoking cessation treatments and reduce safety risks to a very low level. But safety is only one part of the public health calculation—a perfectly safe but relatively ineffective product that few will use will have minimal impact. We also have to consider both the efficacy (how effective is the product as a replacement for smoking) and its appeal (how many people will choose to use it to stop smoking). These consumer products score highly as replacements for smoking because they are not treated as medicines but as substitutes for smoking. Subjecting e-cigarettes and heated tobacco products to an inappropriate regulatory process will protect the combustible cigarette industry and perpetuate smoking among the Filipino population.

Premarket authorizations that mirror pharmaceutical products will amount to de facto prohibition of safer alternatives for smokers, promote black markets, reduce choice and innovation and protect the cigarette trade. An authorization process will require a high level of technical and legal resources and will be open to litigation and possible process abuses. Countries such as the United Kingdom, Canada, the United States and New Zealand have taken pragmatic approaches to e-cigarette and heated tobacco product regulation.³⁶ Rather than prohibiting ENDS, these countries adopted measures such as product and ingredient registration, technical standards, minimum age of purchase laws, limiting points of sale and controls on marketing. Notably, New Zealand recognized the potential of e-cigarettes and heated tobacco products as less harmful alternatives for smokers and reversed their decisions to prohibit sale of these products.³⁷

Protecting Public Health

It is important to recognize that the Government of the Philippines has a role in protecting public health that can be achieved through a variety of regulatory pathways and applications. While the country's smoking rate has decreased since 2010, notably among women and educated and wealthy populations, many are left behind. Low-income populations are more than twice as likely to smoke and less likely to want to quit or be successful at quitting. Allowing new technologies and safer products to evolve in the marketplace has potential to improve the health and welfare of those who cannot or do not want to

³⁶ Government of Canada, "Vaping Product Regulations," May 11, 2020. <https://www.canada.ca/en/health-canada/services/smoking-tobacco/vaping/product-safety-regulation.html>.

Kelly Buchanan, "New Zealand: Bill to Regulate Vaping Introduced," *Library of Congress Law*, March 12, 2020. <https://www.loc.gov/law/foreign-news/article/new-zealand-bill-to-regulate-vaping-introduced/>

³⁷ Kelly Buchanan, <https://www.loc.gov/law/foreign-news/article/new-zealand-bill-to-regulate-vaping-introduced/>

quit combustible cigarettes. In fact, it is estimated that e-cigarettes could save up to 6 million lives by 2100 if only 10 percent of current smokers switch to e-cigarettes over the next 10 years.³⁸

Policies and regulations that treat e-cigarettes the same as combustible cigarettes encourage current smokers to continue doing enormous harm to their health by discouraging a switch from combustible products. Conversely, policies that reflect the reduced harm of e-cigarettes can significantly reduce the burden of disease that combustible cigarettes impose on society.

One thing is certain: We are all striving to improve and protect public health. To do so, we must recognize the potential for e-cigarettes to mitigate risks associated with combustible cigarettes if we wish to encourage a healthful populace. We encourage you to consider policies that reflect the reduced risk of e-cigarettes compared to combustible cigarettes as we work to create a healthier population.

Respectfully submitted,

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³⁸ David T. Levy et al., "Potential deaths averted in USA by replacing cigarettes with e-cigarettes," *Tobacco Control* 27:1 (2017), pp. 18-25. <https://tobaccocontrol.bmj.com/content/27/1/18>.