



The Coalition of Asia Pacific (Tobacco) Harm Reduction Advocates (CAPHRA) submits this white paper to specifically address the issues presented by the government of the Philippines and its ancillary agencies in response to the call for risk proportionate regulation of Safer Nicotine Products (SNP).

We feel, as the regional voice for consumers of SNP in Asia Pacific, that access to these products to adults who wish to utilise them in lieu of combustible tobacco is a human right.

We believe there is a need for government agencies, public health officials and their communities in their respective countries to accept peer reviewed scientific evidence that has studied the use of SNP, its effects on human health.

We believe that public health officials have a mandated responsibility to provide evidence based guidance on best practice with regards to access of these products to adult smokers so they have the information to educate and inform themselves of harm reduced options that are available.

It is in light of this agreed upon mission of information and guidance we address the main concerns presented by the government of the Philippines and the FDA with regards to the risk proportional regulation of Safer Nicotine Products that is currently being discussed.

#### Issues Presented:

**1. Youth Vaping and the “Gateway Effect”** the presumption that youth who vape will go on to using combustible tobacco.

According to Dr. Linda Bauld, who is the lead researcher for the Cancer Research Council and Public Health England on the use of electronic cigarettes in youth and by pregnant women, the data do now show that youth vaping is an “epidemic” as has been touted in the media. Also, **youth who vape are coming to vaping FROM smoking**, not the other way around.<sup>1</sup>

Dr Bauld has stated - repeatedly - that **youth and pregnant women are more inclined to switch to vaping from smoking and not the other way around**. There is no evidence that youth are using vaping as a gateway to smoking. **There is no evidence that the nicotine in electronic cigarettes has the same detrimental effect on pregnant mothers and their children as does smoking during pregnancy.**<sup>2</sup>

Smoking, due to combustion and the 7000 chemicals contained therein, cause health issues. Where there is no “smoke/fire” there are none of the issues that arise from combustion.

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<sup>1</sup> *Int. J. Environ. Res. Public Health* **2017**, *14*(9), 973; <https://doi.org/10.3390/ijerph14090973>

<sup>2</sup> *BMC Pregnancy and Childbirth* **2018***18*:233 <https://doi.org/10.1186/s12884-018-1856-4>



Another study, done in the US entitled “Adolescents and e-cigarettes: Objects of concern may appear larger than they are”<sup>3</sup> by Kozlowski and Warner stated unequivocally that “The role of e-cigarettes in the future of youth smoking has yet to be definitively assessed. **Prospective studies - the only evidence that e-cigarette use might lead to smoking - do not yet persuade that e-cigarettes are a substantial causal gateway to cigarettes.** At best, they support that a minority of the relatively small number of e-cigarette triers - who haven’t also been experimenting with other tobacco products already - will go on to some experimentation with cigarettes”

**Expert: Linda Bauld, PhD (Scotland)**

## **2. Cardiovascular/Cerebral Health Harms (Heart Attack/Stroke) from Vaping.**

Recently there was a study on electronic cigarette users to determine their risk for heart attack and stroke. “*Daily e-cigarette use, adjusted for smoking conventional cigarettes as well as other risk factors, is associated with increased risk of myocardial infarction.*”. In the media, coverage of the conference abstract mention: “*E-cigarettes linked to higher risk of stroke, heart attack, diseased arteries.*” This study<sup>4</sup>, published by the University of Southern California had major flaws in methodology and reporting.

Action on Smoking and Health UK even commented on the problems with the study and conclusions stating “This study does not establish a causal relationship between heart attacks and the use of e-cigarettes. Rather it shows that at the point they were surveyed people who smoked and/or vaped were more likely to have had a heart attack in their lifetime. The study was not able to determine when the heart attack took place, whether it followed or preceded use of an e-cigarette. It is therefore inaccurate to say this research shows that vaping leads to an increased risk of a heart attack. The link between tobacco smoking and heart attacks is well established.”

According to Dr. Konstantinos Farsalinos, a cardiologist and researcher from Greece, “Increasing the risk” means that someone is FIRST exposed to a condition (in this case, exposed to e-cigarette use) and THEN, BECAUSE OF THIS EXPOSURE, he/she develops disease. **Both studies CANNOT provide any of this information to substantiate an increased risk.** Both are cross-sectional surveys, meaning that they asked participants if they have heart disease and if they use e-cigarettes.

**The studies provide no information on whether e-cigarette use was initiated before (and how long before) or after the development of disease.** What if participants used e-cigarettes after they developed the disease in order to quit smoking?

“In conclusion, both studies provide no information about any risk associated with the use of e-cigarettes. **They do not prove an increased risk and of course they do not prove that no such risk exists.** They simply cannot address the question of whether e-cigarettes increase the risk for heart disease or not. I am confident that the authors of the published study and the American Heart Association, which released the press statement for the conference abstract, are very well aware of these basic epidemiological principles. This is simple, basic knowledge for a medical student, let

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<sup>3</sup> <https://www.buffalo.edu/content/dam/www/news/documents/Study%20PDFs/Kozlowski-Warner-DAD-2017-inpress.pdf>, accessed 14Mar19.

<sup>4</sup> Talal Alzahrani, Ivan Pena, Nardos Temesgen, Stanton A. Glantz. Association Between Electronic Cigarette Use and Myocardial Infarction. *Am J Prev Med* 2018; DOI information: 10.1016/j.amepre.2018.05.004.



alone for acknowledged scientists. And they know that the statements about “increased risk” are wrong.”

A five year study done by Dr. Riccardo Polosa, in Italy found that non smokers who vaped, had no increases in markers of cardiovascular risk, lung function and or symptoms of respiratory disease.<sup>5</sup>

Another study done by Dr. Polosa in smokers suggested that E-cigarette (EC) use may ameliorate objective and subjective COPD outcomes and that the benefits gained may persist long-term. EC use may reverse some of the harm resulting from tobacco smoking in COPD patients. These include reduced blood pressure, fewer exacerbations of chronic obstructive pulmonary disease (COPD) and improvements in asthma symptoms.<sup>6</sup>

In the United States, the National Academy of Sciences, Engineering and Medicine published their own report entitled “Public Health Consequences of E-Cigarettes”<sup>7</sup> where they stated clearly that *“There is insufficient evidence that e-cigarette use is associated with long-term changes in heart rate, blood pressure, and cardiac geometry and function.”*

**Experts: Konstantinos Farsalinos, MD (Greece) & Riccardo Polosa, MD (Italy)**

### **3. Concerns around Effects of Second/Third Hand Exposure of Vapour/Aerosol.**

According to experts at the US Department of Health and Human Services, there are no quantifiable harms from second/third hand vapour/there is no additional harms from vaping in those who have been exposed. This has been studied extensively by a few different researchers in different projects.

The first presented is that done by the US Department of Health and Human Services entitled “Evaluation of Chemical Exposures at a Vape Shop”<sup>8</sup> The work involved “Our primary objective was to evaluate employees’ potential exposures to chemicals associated with vaping in the shop. Our work involved (1) sampling air for specific flavoring chemicals associated with respiratory disease; (2) sampling air for nicotine, propylene glycol, formaldehyde, and other VOCs; (3) sampling work surfaces for metals and nicotine; and (4) observing work practices.” The conclusion from the study states “Employees were exposed to detectable levels of diacetyl and 2,3-pentanedione in the air while working in the vape shop. Although the measured concentrations were below all applicable OELs...”

**Expert: US Department of Health and Human Services (USA)**

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<sup>5</sup> Polosa, Riccardo, et al. “Health Effects in COPD Smokers Who Switch to Electronic Cigarettes: a | COPD.” *International Journal of Chronic Obstructive Pulmonary Disease*, Dove Press, 22 Aug. 2018, [www.dovepress.com/health-effects-in-copd-smokers-who-switch-to-electronic-cigarettes-a-r-peer-reviewed-article-COPD](http://www.dovepress.com/health-effects-in-copd-smokers-who-switch-to-electronic-cigarettes-a-r-peer-reviewed-article-COPD).

<sup>6</sup> *ibid.*

<sup>7</sup> “Public Health Consequences of E-Cigarettes.” *Public Health Consequences of E-Cigarettes*, 19 Oct. 2018, [nationalacademies.org/hmd/Reports/2018/public-health-consequences-of-e-cigarettes.aspx](http://nationalacademies.org/hmd/Reports/2018/public-health-consequences-of-e-cigarettes.aspx). Accessed 14Mar19.

<sup>8</sup> <https://www.cdc.gov/niosh/hhe/reports/pdfs/2015-0107-3279.pdf>, accessed 14Mar19



**4. Evidence of Harm Reduction in users of Safer Nicotine Products.** Evidence of Harm Reduction has been scientifically proven, most notably those done and reviewed Public Health England<sup>9</sup> - the National Health Service, the Royal College of Physicians<sup>10</sup> (United Kingdom) and University College and King's College London<sup>11</sup>.

Both of the studies done by University College and King's College London and the Royal College of Physicians have shown a 95-98% reduction in the harm compared to that of combustible tobacco. As Michael Russell said over 30 years ago, it is the TAR that kills, not the nicotine. Alternative nicotine products do not involve combustion, which is what creates TAR.

These studies have been followed up and reviewed regularly by Public Health England, in 2015, 2016 and most recently in 2018. This is the basis for the National Health Service promoting the use of Alternative Nicotine Products in lieu of smoking on hospital grounds in various locations throughout the country, the promotion and use of Alternative Nicotine products within their smoking cessation programs and also the provision of these products in prisons to alleviate the currency of tobacco, as well as the health harms of smoking, to the prisoners and staff.

**Expert: Royal College of Physicians, United Kingdom, UK Centre for Tobacco and Alcohol Studies (UK)**

**5. Concerns that nicotine contained in Alternative Nicotine Products is detrimental to those under the age of 25.** As far back as 2003, researchers were studying and evaluating the effects of nicotine on the adolescent brain and its effects on development. These studies were carried out on adolescents who obtained nicotine via the use of combustible tobacco. **The method of delivery has a distinct effect on the addictiveness of nicotine in both adults and youth, as the chemical constituents of the additives in commercially available combustible tobacco products potentate the addictive qualities of nicotine<sup>12</sup>.**

This is why, in many countries, including the United States, United Kingdom, Canada and New Zealand, the age for prescribing Nicotine Replacement Treatment begins as early as 12 years old, based on a recommendation from the American Cancer Society, in 2010, that stated **“that youth (ages 12-18) be included in smoking cessation initiatives, recognizing that support and**

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<sup>9</sup> Public Health England. “E-Cigarettes and Heated Tobacco Products: Evidence Review.” *GOV.UK*, GOV.UK, 2 Mar. 2018, [www.gov.uk/government/publications/e-cigarettes-and-heated-tobacco-products-evidence-review](http://www.gov.uk/government/publications/e-cigarettes-and-heated-tobacco-products-evidence-review).

<sup>10</sup> “Nicotine without Smoke: Tobacco Harm Reduction.” *RCP London*, 25 July 2017, Accessed 14 Mar 19 [www.rcplondon.ac.uk/projects/outputs/nicotine-without-smoke-tobacco-harm-reduction-0](http://www.rcplondon.ac.uk/projects/outputs/nicotine-without-smoke-tobacco-harm-reduction-0).

<sup>11</sup> Goniewicz, Maciej L., et al. “Nicotine, Carcinogen, and Toxin Exposure in Long-Term E-Cigarette and Nicotine Replacement Therapy Users: A Cross-Sectional Study.” *Annals of Internal Medicine*, American College of Physicians, 21 Mar. 2017, [annals.org/aim/article-abstract/2599869/nicotine-carcinogen-toxin-exposure-long-term-e-cigarette-nicotine-replacement](https://annals.org/aim/article-abstract/2599869/nicotine-carcinogen-toxin-exposure-long-term-e-cigarette-nicotine-replacement).

<sup>12</sup> Klesges, Lisa M. “Use of Nicotine Replacement Therapy in Adolescent Smokers and Nonsmokers.” *Archives of Pediatrics & Adolescent Medicine*, American Medical Association, 1 June 2003, [jamanetwork.com/journals/jamapediatrics/fullarticle/481346](http://jamanetwork.com/journals/jamapediatrics/fullarticle/481346).



encouragement are important for this age group in particular.”<sup>13</sup> Nicotine, in and of itself, outside of combustible tobacco, is no more addictive than caffeine<sup>14</sup>.

It needs to be noted that in the Philippines, there is no age restriction on the prescribing of NRT to youth. NRT is also readily available over the counter in the entire country and there is no requirement for age verification.

Therefore, two main features are at play here with regards to the claim that nicotine is dangerous to the developing brain - the first is that nicotine, as delivered through combustible tobacco, is potentiated by the additives and processing of combustible tobacco products and that the combustion itself is what is detrimental to this method of delivery; secondly, the provision of Nicotine Replacement Therapy to adolescents has been shown to NOT be detrimental to the developing adolescent brain, hence the recommendation to prescribe NRT to youth smokers.

Lastly, the age of adolescence, in the global medical field, is from the age of 12-18. If combustible tobacco products are available to adults 18 and over, there is no reason why the harm reduced alternatives of nicotine consumption should be restricted differently.

**Expert: Royal Society of Physicians (UK), National Cancer Society (United States)**

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<sup>13</sup> Karpinski, Julie P, et al. “Smoking Cessation Treatment for Adolescents.” *The Journal of Pediatric Pharmacology and Therapeutics : JPPT : the Official Journal of PPAG*, Pediatric Pharmacy Advocacy Group, 2010, [www.ncbi.nlm.nih.gov/pmc/articles/PMC3042263/](http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3042263/).

<sup>14</sup> RSP-UK. “Nicotine ‘No More Harmful to Health than Caffeine.’” *RSPH*, [www.rsph.org.uk/about-us/news/nicotine--no-more-harmful-to-health-than-caffeine-.html](http://www.rsph.org.uk/about-us/news/nicotine--no-more-harmful-to-health-than-caffeine-.html).