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DR. ROLANDO ENRIQUE D. DOMINGO, M.D.

Director General

Food and Drug Administration

Civic Drive, Filinvest Corporate City

Alabang, Muntinlupa City

Philippines

ntru@fda.gov.ph

cf Rep. Wes Gatchalian,

Chairperson of the Committee on Trade and Industry of the House of Representatives

trade_hor@yahoo.com

cf Secretary Ramon Lopez,

Department of Trade and Industry

secretary@dti.gov.ph

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

Honourable Sirs:

I am writing to you as founder of factasia, a not-for-profit regional consumer advocacy, in relation to the FDA draft General Guidelines of Vapor Products and Heated Tobacco Products.

Having studied the draft guidelines, we find several aspects of the proposed policy to be extremely troubling. While we can applaud the sentiments behind the initiative, we cannot endorse or support policies that are unaligned with unbiased scientific research, ignore empirical evidence and further restrict the rights and choices of adult smokers to transition to alternative nicotine products that are proven to be much safer than deadly cigarettes – both to users and non-users.

We would therefore like to address several items in the draft starting with possibly most contentious position that the FDA draft proposes, that of treating all vaping and HTPs as health products. They are NOT health products, and this flawed strategy has been discontinued in many countries after having been identified as a cynical ‘back door ban’ that serves only the vested interests of pharmaceutical companies and their NRTs rather than the those of smokers and their families, friends and colleagues.

The first point that needs to be made is that alternative nicotine products, such as vape and heat not burn (HNB) products, are not and never will be medical or health products. They cannot be classified as medicines as they neither treat nor mitigate a disease. Therefore it would be impossible for any product in these categories to attain the necessary clearances to be sold as

medication or health products, which is clearly what those who are opposed to tobacco harm reduction and consumer choice intend, thereby protecting the market for pharmaceutical companies' 'Nicotine Replacement Therapies', which have time and again, in independent study after independent study, been proven to be much less effective at getting smokers off cigarettes than vapes and HNB.

The burden that imposing such impossible Pharmaceutical industry-specific requirements on E-cigarette and heated tobacco product manufacturers, importers and retailers will not only cause massive economic disruption it will also deprive MILLIONS of Filipino smokers the opportunity to choose to transition away from smoking to these much less harmful products – and drive many current vapers back to smoking deadly cigarettes. 'Medicalizing' harm reduced nicotine products is akin to requiring doctors' prescriptions for alternative consumer products such as calorie-free sweeteners, processed foods, diet sodas, energy drinks, soy milk, seat belts, crash helmets, condoms, etc.

Cigarettes are legally available to all adults as a consumer product, albeit highly regulated and taxed, without any requirement to comply to such regulatory oversight. They are sold alongside pharmaceutical companies' NRTs openly and legally at convenience stores and other outlets. Vapes and HNB are also consumer products, ones that replace the deadly, carcinogenic conventional tobacco cigarettes with far less harmful consequences to users and those around them. Why on earth would you seek to medicalize a much safer replacement for a perfectly legal, non-medicalized consumer product (cigarettes) that kills 50% of smokers prematurely and spreads disease and sickness to passive smokers around them? Vape and HNB do NONE of these things, they significantly and effectively REDUCE THE HARM caused by smoking and benefit not only users but society as a whole by reducing the health care burden and loss of productivity smoking-related illnesses create.

To be clear: there has NEVER been a recorded death from vaping regulated nicotine products since the introduction of the e-cigarette in 2001. But over the same period of time, more than 130 MILLION smokers have died from tobacco-related illnesses and disease.

Smoking is not a disease, it is a habit. A habit that has long term health consequences. Nicotine dependency is NOT an illness. Nicotine itself is not a particularly harmful compound, as even the WHO has admitted when it suggested smokers having a hard time quitting smoking using pharmaceutical companies NRTs can continue using nicotine patches, sprays and gums *ad infinitum*. WHO has stated clearly that: "there are no known health consequences associated with long-term nicotine use". This position is echoed by many other leading health bodies including the UK's Public Health England (PHE). It is the smoke in cigarettes that kills smokers, NOT the nicotine.

Imposing the 'health' standards FDA is proposing would inevitably set harm reduction and tobacco control initiatives in the Philippines back by 20 years by creating a *de facto* ban on vape and HNB.

For example, banning the use of propylene glycol and glycerol (both of which are widely used in the pharmaceutical and food and beverage industries) would sound the death knell to the production and development of reduced harm nicotine alternatives – and while this may be in line with the aims of the vested interests who seek to destroy the less harmful nicotine segment to protect their own commercial interests, it is in no way helpful to the millions of Filipinos who smoke and who wish to quit but find it hard to do so using ‘approved’ quit or die methods. It also denies the facts and evidence that clearly show such products to be far less harmful than smoking and far more effective than conventional NRTs at getting smokers to quit, not to mention denying adult consumers of the right to access such products, at great cost to their health and to society in general.

A flavour ban other than tobacco (note: there is NO tobacco used in the production of tobacco flavours used in vapes) and menthol simply serves to make vaping less appealing to adult smokers and will not serve to re-educate their palates away from the very flavours associated with smoking that they are trying to avoid.

Limiting the amount of nicotine is another contentious issue. There are no such limits imposed on combustible products: to impose such limits on nicotine in vapes is unhelpful... it has been demonstrated for years that the lower the nicotine content of a cigarette, the more cigarettes a smoker requires to meet their body’s cravings. The same is also true for vaping and HNB. If you restrict the amount of nicotine users can access in their devices, they will inevitably consume more to achieve the satisfaction they crave.

Denying consumers the option to choose to buy products and supplies online, and particularly requiring them to apply for an ‘FDA ID’ to be able to purchase vapes or HNB is also a huge leap backwards. There is no such requirement for smokers to acquire an FDA ID, why on earth would anyone think it would be appropriate to impose such harsh demands on citizens trying to escape from deadly combustible tobacco products to significantly less harmful alternatives?

Most smokers started smoking at an early age, well before they reach adulthood and gained the capacity to make informed decisions, and by the time they realized that it is harming them, it is extremely difficult for most to simply quit. Vaping and HNB have helped many millions of former smokers to transition away from cigarettes permanently by exercising their choice to adopt these far less harmful products and completely stop using deadly tobacco products. This is an example of Harm Reduction at its finest.

We treat addictions such as alcoholism and drug dependency using a variety of interventions, many of which employ the proven and effective strategy of Harm Reduction. Seat belts, crash helmets, condoms, water filters - these are all examples of harm reduction.

Harm reduction, together with the right to health, is enshrined in both the WHO and FCTC mission statements on tobacco control. The fact that many FCTC delegates choose to ignore this fact and continue to deny the science and the core obligations of their mission statement does not mean that clear-thinking, open-minded regulators who are willing to study the independent, unbiased evidence need to follow this egregious denial of basic rights and common sense and deny their citizens the right to choose less harmful alternatives to smoking.

As the draft regulations stand, they seem to be designed to deny 16.6 million Filipino smokers access to less harmful alternatives, driving many who have successfully quit smoking thanks to these disruptive technologies back to smoking and criminalizing many of those that choose to continue using vapes and HNB because they understand that their right to health and personal choice is a better option than following arbitrary, unjustified and restrictive legislation.

It is our view that the current draft has been designed to restrict if not prohibit access to less harmful alternatives to smoking and is completely undemocratic. Adult smokers should have the right to be accurately and fully informed about less hazardous alternatives to cigarettes and to have access to them, and even encouraged to try them, as is the case in countries, such as the UK and Canada, which have studied all the evidence and applied appropriate regulations. This strategy has demonstrated unequivocally that these adult consumer harm reduced products are game-changers when it comes to significantly lowering smoking rates and reducing the death and disease caused by smoking.

Accordingly, while it is self-evident that less harmful nicotine products should NOT be made available to minors, we would urge the FDA to consider more effective, evidence-based, proportional, rational and reasonable solutions, including for the government to regulate the manufacture, import and sale of these products in line with mandatory standards for quality, safety, and performance adopted internationally for every other consumer product on the market.

Rather than seeking to ban or outlaw or severely restrict access to these life-changing alternatives to smoking, the FDA should consider making accurate and factual information available to smokers so they can make informed decisions and access these products as part of their efforts to quit smoking.

To summarize, we urge the FDA to consider the following:

1. Accept the body of evidence from the anti-smoking and harm reduction experts. Restricting adult access to safer products is unethical and counter-productive in the battle to eliminate the death and disease associated with smoking.
2. Legalise e-cigarette use in the Philippines among adults, as has been legislated in countries such as the UK and in the EU where E-cigarettes and other non-combustible alternatives are understood



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by Public Health authorities to be much less harmful to smokers and eliminate passive smoking concerns to non-smokers.

3. Regulate for product quality and manufacturing standards like any other consumer product, and tax rationally – no-one is suggesting e-cigarettes should be tax-exempt.

4. Underage use of vaping devices can and should be prohibited, it has always been within the power of the government to enact specific legislation in this regard. However, adult smokers should not be disadvantaged by regulations aimed at preventing youth uptake and a full range of products should be made available to adult smokers seeking to transition to less harmful alternatives to smoking.

5. In line with international best-practices policy development, the Philippine Government should continue to ensure that appropriate public consultation and a regulatory impact assessment be undertaken before any legislation is amended.

The Government has a chance to become a clear leader in Asia in progressive public health policy and in harm reduction in this vital sector. It is what consumers want, and it's good for them too.

About factasia

factasia.org is an independent, not-for-profit, consumer-oriented advocate for rational debate about – and sensible regulation of – the rights of adult citizens throughout the Asia-Pacific region to choose to use tobacco or other nicotine related products.

factasia does not promote smoking or the use of nicotine, opposes all under-age use of cigarettes or any other product containing nicotine, and does not engage in any manufacturing, marketing, distribution or retailing activities.

factasia's role is to act as a messenger, facilitating constructive dialogue between scientists and medical experts, legislators, regulators and the general public.

APPENDIX 1

The enclosed online bibliography is a selection of THR evidence/science published in peer reviewed journals from 2019/2018 from across the globe.

[Moderators of real-world effectiveness of smoking cessation aids: a population study](#)

[Smokeless tobacco mortality risks: an analysis of two contemporary nationally representative longitudinal mortality studies](#)

[E-cigarettes and smoking cessation in the United States according to frequency of e-cigarette use and quitting duration: analysis of the 2016 and 2017 National Health Interview Surveys](#)

[Vaping in England: an evidence update February 2019](#)

[A Randomized Trial of E-Cigarettes versus Nicotine-Replacement Therapy](#)

[Patterns of e-cigarette use, biochemically verified smoking status and self-reported changes in health status of a random sample of vape shops customers in Greece](#)

[Comparing the cancer potencies of emissions from vaporized nicotine products including e-cigarettes with those of tobacco smoke](#)

[Comparison of nicotine and toxicant exposure in users of electronic cigarettes and combustible cigarettes](#)

[The unique contribution of e-cigarettes for tobacco harm reduction in supporting smoking relapse prevention](#)

[How do we determine the impact of e-cigarettes on cigarette smoking cessation or reduction? Review and recommendations for answering the research question with scientific rigor](#)

[Prevalence of population smoking cessation by electronic cigarette use status in a national sample of recent smokers](#)

[E-cigarettes: Balancing risks and opportunities](#)

[E-cigarette usage is associated with increased past-12-month quit attempts and successful smoking cessation in two US population-based surveys](#)

[E-cigarettes: Comparing the possible risks of increasing smoking initiation with the potential benefits of increasing smoking cessation](#)

[Managing nicotine without smoke to save lives now: Evidence for harm minimization](#)

[Evidence review of e-cigarettes and heated tobacco products 2018](#)

[Potential deaths averted in USA by replacing cigarettes with e-cigarettes](#)

[E-cigarette initiation and associated changes in smoking cessation and reduction: The population assessment of tobacco and health study, 2013–2015](#)

[Examining the relationship of vaping to smoking initiation among US youth and young adults: A reality check](#)

[Acute impact of active and passive electronic cigarette smoking on serum cotinine and lung function](#)

APPENDIX 2

2016 ASIAN NATIONS ADULT SMOKER E-CIGARETTE SURVEY PHILIPPINES EXECUTIVE SUMMARY SEPTEMBER 2016

The results contained in this report are derived from a face-to-face survey conducted from July 26 – August 9, 2016 among adult smokers aged 18+ in metro Manila, metro Cebu, and metro Davao. A total of 600 interviews were conducted by Ipsos on behalf of factasia.org. This study carries a margin of error of $\pm 4.0\%$ at the 95% confidence level.

The full survey results are available [HERE](#)

Smokers and E-cigarettes in the Philippines

- E-cigarette usage is low in the Philippines, with regular and occasional users totaling just 4% of adult smokers. Fully 85% are complete non-users of e-cigarettes.
- Nearly half (49%) of regular and occasional users have been using e-cigarettes for less than three months.
- Among occasional e-cigarette users, 43% say the price of e-cigarettes has kept them from using the product more. Further, 21% say accessibility is a reason, while 20% say flavor has kept them from using e-cigarettes more frequently.

Awareness and Understanding of E-cigarettes

Two-thirds (66%) of adult smokers in the Philippines are aware of e-cigarettes. Furthermore, awareness increases with education and income and decreases with age.

A majority are familiar with e-cigarettes (58%), but a notable 29% said they were “not at all familiar” with the product.

While two-thirds of adult smokers in the Philippines are aware of e-cigarettes, familiarity is slightly lower. Smokers are more likely to be “not at all familiar” with e-cigarettes than “very familiar” with them.

Regulation of E-cigarettes

- The vast majority of adult smokers (86%) agree they should have the right to access information about less harmful alternatives to cigarettes, with all e-cigarette users agreeing (100%).

- Three-fourths (76%) agree the Government should be encouraging them to switch to less harmful products by easing fiscal and regulatory policies. While less united in their opinions about the Government delaying or preventing the introduction of less harmful alternatives, most adult smokers (63%) still agree that delay or prevention would be wrong. Despite low instances of e-cigarette usage and some confusion about the product, adult smokers are largely in agreement about the Government's role regarding less harmful alternatives: access to information about less harmful alternatives should be provided, taxes and regulations on alternatives should ease to encourage smokers to switch, and delay or prevention of the introduction of alternatives would be wrong.

E-cigarettes as an Alternative

- Seven-in-ten adult smokers (70%) agree that "e-cigarettes represent a positive alternative to today's conventional cigarettes."
- Agreement increases to 78% among those familiar with e-cigarettes.
- Similarly, seven out of ten (70%) adult smokers would consider "switching to e-cigarettes if they were legal, met quality and safety standards, and were conveniently available like regular tobacco products."
- Younger adult smokers are significantly more likely to see e-cigarettes as a positive alternative and to consider switching to them compared to those 40 years and above.

Not only do adult smokers in the Philippines recognize that e-cigarettes are a positive alternative to conventional cigarettes but, given the opportunity, many would also consider switching to less harmful alternatives.