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Dr. Rolando Enrique D. Domingo, M.D.
Director General
Philippine Food and Drug Administration
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Filinvest Corporate City
Alabang 1781 Muntinlupa City
Philippines

Comment: FDA Draft General Guidelines for the Regulation of Vapor Products and Heated Tobacco Products.

Dear Director General Domingo,

On behalf of the more than one million members and supporters of Citizens Against Government Waste (CAGW) in the United States, I am writing to express our disappointment over the Philippine Food and Drug Administration's (FDA) draft guidelines, "Regulation of Vapor Products and Heated Tobacco Products."

CAGW is a private, nonpartisan, nonprofit, organization whose mission is to eliminate waste, fraud, abuse, mismanagement, and inefficiency in government. Founded in 1984 by the late industrialist J. Peter Grace and syndicated columnist Jack Anderson, CAGW was established to follow up on President Reagan's Private Sector Survey on Cost Control, also known as the Grace Commission.

The Philippine FDA is mandated to "periodically determine and regulate, consistent with evolving medical and scientific studies, the manufacture, importation, sale, packaging, advertising, and distribution of vapor products and heated tobacco products (HTPs), including banning of flavors, and the sale to nonsmokers or persons below twenty-one (21) years old."

Part of the rationale in the guidelines for the regulation of vapor products and heated tobacco products is, "Vapor products, including Electronic Nicotine and Non-nicotine Delivery Systems (ENDS/ENNDS), and HTPs are a form of health products used to deliver aerosolized substances to the lungs by mimicking the act of smoking." The FDA has wide discretion on how to regulate these products. CAGW believes it is a mistake to regulate them as a health product, like pharmaceuticals or medical devices. Vaping and heat-not-burn technologies are not healthcare products but are a harm reduction product. They are a successful and useful method to use in weaning smokers away from harmful combustible cigarettes, which are known to cause serious diseases like cancer and COPD.

To treat and regulate ENDS as health products would create a complex and unworkable regulatory system where manufacturers, retailers, and importers would be unable to produce and access them and would instead continue to manufacture and sell only combustible cigarettes. Smokers would continue to use combustible cigarettes or turn to black-market products. This would be unfortunate because according to the Philippine Department of Health, and based on World Health Organization statistics, the Philippines "continues to have one of the highest rates of smoking in Asia despite the government's efforts to get Filipinos to quit smoking" and is in one of the "top 15 countries worldwide with the highest burdens of tobacco related illnesses."

CAGW is also concerned that the ENDS regulations state that "all flavors other than plain menthol and plain tobacco shall not be allowed for use in vapor product refills." People who vape rely on a variety of flavors because it helps them break the smoking habit and enables them to stay smoke-free.

CAGW believes health agencies in every country, including the U.S. FDA and the U.S. Centers for Disease Control and Prevention (CDC), should take a more realistic view and admit that people will continue to smoke unless provided with many viable options, including harm-reduction products like ENDs, to quit.

Public Health England (PHE) has taken the lead in proving that smokers switching to harm-reduction products like vaping or heat-not-burn technologies help people quit smoking and save lives, which CAGW assumes is also the goal of your agency.

A study of nicotine replacement therapy, funded by the British National Institute for Health Research and Cancer Research and published in the February 14, 2019 *New England Journal of Medicine*, found that e-cigarettes were twice as effective as nicotine patches or gum to help smokers quit cigarettes. The 1-year abstinence rate was 18.0 percent in the e-cigarette group, as compared with 9.9 percent in the nicotine-replacement group.

A February 2018 PHE independent review found that:

- "vaping poses only a small fraction of the risks of smoking and switching completely from smoking to vaping conveys substantial health benefits
- e-cigarettes could be contributing to at least 20,000 successful new quits per year and possibly many more
- e-cigarette use is associated with improved quit success rates over the last year and an accelerated drop in smoking rates across the country
- many thousands of smokers incorrectly believe that vaping is as harmful as smoking; around 40% of smokers have not even tried an e-cigarette
- there is much public misunderstanding about nicotine (less than 10% of adults understand that most of the harms to health from smoking are not caused by nicotine)
- the use of e-cigarettes in the UK has plateaued over the last few years at just under 3 million
- the evidence does not support the concern that e-cigarettes are a route into smoking among young people (youth smoking rates in the UK continue to decline, regular use is rare and is almost entirely confined to those who have smoked)"

A major part of England's Department of Health July 2017 tobacco-control plan, "Towards a Smokefree Generation," is to not only permit but also encourage the use of safer alternatives to smoking, like e-cigarettes. England's health officials recognize evidence is growing that these technologies are significantly less harmful to health than combustible cigarettes.

PHE's proactive view on the use of electronic nicotine delivery systems has helped more than one million smokers in England quit their deadly habit since 2014. At the rate England is proceeding, PHE has predicted that by 2030, England will be classified as smoke-free, which is less than 5 percent of the population.

To be clear, CAGW is disappointed with the U.S. FDA's approach to the use of ENDS. CAGW believes U.S. FDA's actions to ban certain flavors in ENDS products and its lengthy, complicated, and incoherent regulatory actions concerning the marketing of vaping products and other harm reducing ENDS products will destroy large segments of this innovative industry, encourage the growth of a dangerous black market for these products, and ultimately hurt smokers who are trying to move away from combustible cigarettes.

We urge the Philippine FDA to avoid following an even more restrictive course of action.

Sincerely,

cc:

Rep. Wes Gatchalian
Chairperson of the Committee on Trade and Industry
House of Representatives

Secretary Ramon Lopez
Department of Trade and Industry