September 27, 2017

Commissioner Scott Gottlieb
Food and Drug Administration
10903 New Hampshire Ave
Silver Spring, MD 20993

Dear Commissioner Gottlieb,

We the undersigned organizations dedicated to improving public health, increasing consumer choice, and reducing taxpayers' burden through innovation, encourage you to bring less harmful tobacco products to the market expediently. By doing so, the Food and Drug Administration (FDA) would signal that it values cutting edge, harm-reducing technologies that will undoubtedly offer health benefits for individual consumers and the nation at-large.

The FDA is currently reviewing the **Modified Risk Tobacco Product Application** (Docket FDA-2017-D-3001), published on June 15, 2017.

Traditional cigarettes are a known hazard to health, but the risks stem mainly from chemicals produced through the process of combustion. Products that heat nicotine solutions or tobacco, such as the IQOS, deliver nicotine without combustion and, as a result, lack most of the harmful and potentially harmful elements of traditional tobacco. Heat-not-burn alternatives provide substantially less hazardous options for individuals wishing to consume nicotine with an experience similar to smoking. In 2014, the FDA's own research determined, "the inhalation of nicotine (i.e. nicotine without the products of combustion) is of less risk to the user than the inhalation of nicotine delivered by smoke from combusted tobacco products."[1]

The history of technology is full of examples where innovation moves consumers toward safer, more effective, and more user-friendly options. We've seen innovations in public health elsewhere, as wearable tech like Fitbit and Apple Watch change the way we exercise and monitor our health. Telemedicine has increased access to medical services in remote and underserved areas. Companies like Zipline are using drones to deliver medicine in Rwanda, overcoming a lack of roads and other infrastructure challenges. These advances bypass conventional outmoded paradigms and create new ones, and they have occurred in all aspects of American life.

Even in tobacco, countries that adopted the use of existing non-combustible products have already seen the health

1 Deeming Tobacco Products To Be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Restrictions on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products 81 FR 28973 (May 10, 2016), *available at* https://www.gpo.gov/fdsys/pkg/FR-2016-05-10/pdf/2016-10685.pdf.

benefits of allowing consumers access to reduced-harm options. For example, Swedish men have the highest rates of snus use (a moist tobacco chew) in the European Union.[2] Consequently, Swedish men also have the lowest lung-cancer rates[3] and one of the lowest rates of both oral[4] and esophageal[5] cancers in the EU.

In the market for nicotine-delivery, the latest technological innovations are inhalable, but non-combustible products like IQOS. As with Swedish snus, research finds that these products are many orders of magnitude safer than traditional cigarettes.[6,7] Such innovations within the tobacco market ought to be welcomed by the FDA as having the potential to disrupt—for the better—the "analog" approach to public health.

Over the past decade, the electronic vapor industry (aka e-cigarettes) has grown from an online novelty to a brick-and-mortar industry worth more than $8 billion a year. By 2025 it is estimated the global market will be nearer to $47 billion.[8] As millions switch from smoking to vaping, we're experiencing a mass movement from a harmful analog product—cigarettes— to demonstrably safer digitized products. This large-scale voluntary transition demonstrates a consumer desire for reduced-harm nicotine products and should be embraced by regulators as a development with the potential to improve and save millions of lives.

Given how difficult it is to quit smoking, it is imperative the FDA acknowledge that there is no single approach to cessation that works for everyone. The diversity and variety seen in vapor products is a key reason for their success in pushing smokers to safer nicotine-delivery systems. For example, adult users who were able to reduce or eliminate their traditional tobacco use self-report the availability of a variety of flavors as being "very important" to their success.[9] However, e-cigarettes don't work for everyone, especially those that prefer the taste of real tobacco to the flavors of e-vapor liquid. Heat-not-burn products provide an experience similar to smoking while still substantially reducing users' and bystanders' exposure to harmful and potentially harmful chemicals. While not "risk free," both industry-funded and non-industry research indicate that heat-not-burn tobacco products like the IQOS deliver less of the known toxic chemicals, upwards of 90 percent less, than combustible cigarettes—a reduction in harm that is less than, but similar to, the reduction observed in electronic cigarettes.[10,11]

Government policy has a huge impact on whether consumers understand the *relative risks* of various products and whether or not they adopt safer alternatives. Concerted efforts among government health organizations to raise awareness about the potential harms associated with electronic cigarettes, well-intentioned as they may be, have resulted in the growing number of consumers who fundamentally misunderstand the risks of using alternative tobacco products *as compared* to traditional cigarettes. Polling data from 2015 found that 35 percent of Americans viewed these demonstrably safer products as being "as harmful" as traditional cigarettes, while just 12 percent held this misinformed belief three years prior.[12] At the same time, health authorities in other nations have adopted re-

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2 Greenhalgh, EM, Bayly, M, & Winstanley, *MH. 1.13 International comparisons of prevalence of smoking, Tobacco in Australia: Facts and issues*, Melbourne: Cancer Council Victoria; (November 2015), *available at* http://www.tobaccoinaustralia.org.au/chapter-1-prevalence/1-13-international-comparisons-of-prevalence-of-sm.

3 World Health Ogranization, *Lung cancer including trachea and bronchus, Estimated Incidence, mortality & prelevance, 2012*, International Agency for Research on Cancer Eucan (2012) eco.iarc.fr/eucan/Cancer.aspx?Cancer=18.

4 World Health Ogranization, *Cancer of lip, oral cavity and pharynx 2012*, International Agency for Research on Cancer Eucan (2012), http://eco.iarc.fr/eucan/Cancer.aspx?Cancer=1.

5 World Health Ogranization, *Oesophageal cancer*, International Agency for Research on Cancer Eucan (2012), http://eco.iarc.fr/eucan/Cancer.aspx?Cancer=7.

6 Advisory Group of the Royal College of Physicians, Protecting smokers, saving lives: The case for a tobacco and nicotine regulatory authority 2-5 (2002).

7 McNeill A, Brose LS, Calder R, Hitchman SC, Hajek P and McRobbie H, "Electronic cigarettes and smoking; e-cigarettes: an evidence update" (2015) *available at* https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/457102/Ecigarettes_an_evidence_update_A_report_commissioned_by_Public_Health_England_FINAL.pdf.

8 Diana Caruana, *Global vaping market to reach $47 Billion by 2025*, Vaping Post (April 25, 2017), https://www.vapingpost.com/2017/04/25/global-vaping-market-to-reach-47-billion-by-2025/

9 Farsalinos K, et al. Impact of Flavour Variability on Electronic Cigarette Use Experience: An Internet Survey. *International Journal of Environmental Research and Public Health*. 2013 Dec; 10(12): 7272–7282. doi: 10.3390/ijerph10127272, *available at* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3881166.

10 Lüdicke F, et al., *Reduced exposure to harmful and potentially harmful smoke constituents with the tobacco heating system 2.1.*, Nicotine & Tobacco Research (February 2017) 19(2): 168–175, available at http://bit.ly/2wJgVPo.

11 Auer R., *Heat-Not-Burn Tobacco Cigarettes: Smoke by Any Other Name*, JAMA Internal Medicine. (July 2017) 1;177(7):1050-1052, *available at* http://bit.ly/2wrzpEu.

12 Majeed B, et al. Changing Perceptions of Harm of E-Cigarettes Among U.S. Adults, 2012-2015. *American Journal of*

duced-harm tobacco products as part of the solution to tobacco harm. While government health bodies are charged with protecting consumers from potentially harmful products, consumers deserve truthful information about relative risks of various options so that they may make the important decisions that will affect their health.

In July, the British government unveiled a plan to reduce smoking rates among adults to 12 percent by the end of 2022. The plan, called "Towards a smoke-free generation: tobacco control plan for England," notes that "Two thirds of smokers say they want to stop smoking, however long term success rates are low." Innovative nicotine-delivery alternatives are proving successful in facilitating smoking cessation and getting smokers to adopt less harmful alternatives.

According to the U.K. report, "In 2016 it was estimated that 2 million consumers in England had used (*alternative nicotine delivery system*) products and completely stopped smoking and a further 470,000 were using them as an aid to stop smoking."

As a result of this success, the U.K. Department of Health declared that they "welcome innovation that will reduce the harms caused by smoking and will evaluate whether products such as novel tobacco products have a role to play in reducing the risk of harm to smokers."[13] The United States, and the FDA, should follow the U.K.'s lead in embracing marketplace innovations and encouraging smokers to switch to those alternatives.

In Japan, where IQOS has been on the market since April 2016, a peer-reviewed research study by the Osaki Hospital Tokyo Heart Center found that smokers who switched to IQOS:

- Reduced their exposure to 15 harmful chemicals to levels that approached those of smokers who quit smoking;
- Showed improvements in measured health indicators specific to smoking-related diseases, such as lung and heart disease. In all cases, the health indicators improved in the same direction as seen in smokers who quit; and
- Found the product satisfying and were likely to completely switch to it.[14]

For smokers that haven't already quit using e-vapor, Nicorette, pharmaceuticals, hypnosis, or the other currently available cessation methods, the IQOS system may prove to be best option for them—a potentially effective new tool among the imperfect solutions to a difficult public health epidemic.

We encourage the FDA to reduce regulatory barriers to human progress and foster these market innovations that contribute positively to our community. The FDA has not just an opportunity, but a responsibility, to allow technological progress to continue creating new options that reduce the harmful health effects of smoking by allowing heat-not-burn tobacco options to meet consumer demand. We urge the FDA to approve the MRTP application for IQOS, and we also encourage the agency to approve any future innovations that can benefit public health.

We further request a meeting with you or your designee to discuss these concerns.

Sincerely,

TechFreedom
Taxpayers Protection Alliance
CEI
CASAA
Citizens Against Government Waste
Log Cabin Republicans
National Center for Public Policy Research
Not Blowing Smoke

Preventative Medicine. 2017 Mar;52(3):331-338. doi: 10.1016/j.amepre.2016.08.039.

13 UK Department of Health, *Towards a smoke-free generation: tobacco control plan for England*, Gov.Uk (July 2017), *available at* https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/630217/Towards_a_Smoke_free_Generation_-_A_Tobacco_Control_Plan_for_England_2017-2022__2_.pdf.

14 Frank Lüdicke, MD Patrick Picavet, MD Gizelle Baker, PhD Christelle Haziza, PhD Valerie Poux, MSc Nicola Lama, PhD Rolf Weitkunat, PhD, *Effects of Switching to the Menthol Tobacco Heating System 2.2, Smoking Abstinence, or Continued Cigarette Smoking on Clinically Relevant Risk Markers: A Randomized, Controlled, Open-Label, Multicenter Study in Sequential Confinement and Ambulatory Settings*, Nicotine & Tobacco Research (April 2017) available at https://academic.oup.com/ntr/article-lookup/doi/10.1093/ntr/ntx028.