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Testimony from:
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In OPPOSITION to Bill 23-0453, "Flavored Electronic Smoking Device Prohibition Amendment Act of 2019."

February 24, 2020

Dear Chairman Allen and the Members of the Committee on The Judiciary & Public Safety,

We write to you out of continuing concern regarding the proposed ban on sales and distribution of flavored e-cigarettes. This concern arises from the fact that the restriction of flavors in far less harmful alternatives may deter smokers from switching away from combustible cigarettes. In our opinion, it is beyond any reasonable doubt that such products are much less harmful than smoking and that switching from smoking to vaping provides significant benefits to individuals' health.

Public Health England[1]; the National Academies of Science, Engineering and Medicine[2]; and the FDA[3] have recognized nicotine products exist on a continuum of risk, with e-cigarettes 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, Public Health England stated that e-cigarettes are unlikely to exceed 5 percent of the risk associated with combustible cigarettes.[4]

In their 2018 report, the National Academies conclude that 1) "There is conclusive evidence that completely substituting e-cigarettes for combustible tobacco cigarettes reduces users' exposure to numerous toxicants and carcinogens present in combustible tobacco cigarettes,"[5] and 2) "There is

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[1] RCP policy: public health, *Nicotine without smoke: Tobacco harm reduction*, Royal College of Physicians, April 28, 2016. https://www.rcplondon.ac.uk/projects/outputs/nicotine-without-smoke-tobacco-harm-reduction-0.

[2] "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."

[3] 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, 2018. 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."

[4] Tobacco Advisory Group, "Nicotine without smoke: tobacco harm reduction," Royal College of Physicians, 2016. p. 87. https://www.rcplondon.ac.uk/projects/outputs/nicotine-without-smoke-tobacco-harm-reduction-0.

[5] "The Public Health Consequences of E-cigarettes," National Academies of Science, Engineering and Medicine, January 2018. pp. 604. http://nationalacademies.org/hmd/reports/2018/public-health-consequences-of-e-cigarettes.aspx.

substantial evidence that completely switching from regular use of combustible tobacco cigarettes to e-cigarettes results in reduced short-term adverse health outcomes in several organ systems."[6]

Furthermore, there is a substantial body of evidence that e-cigarettes help smokers quit smoking. The reason this method is so promising is not just its effectiveness, which is better compared to other methods. It can also reach more smokers, including those who may not wish to quit using traditional methods or may not wish to quit using nicotine at all. It is not an alternative, but an *addition* to the available ways to quit smoking.

E-cigarettes have quickly become the number one quit 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. In the United States and the United Kingdom e-cigarettes have outpaced traditional quit methods (varenicline, nicotine replacement therapies and counseling)[7] and demonstrate a higher degree of success.[8] Finally, 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.[9]

Evidence does not support the claim that e-cigarettes may act as a gateway to combustible use—there have generally been sharp declines in youth and adult smoking where vaping has increased, and regular vaping is highly concentrated in young people who already smoke.[10]

However, we do share the committee's concerns that youth use of e-cigarettes needs to be addressed, and we believe there are several ways to do this without resorting to a comprehensive flavor ban. Many steps have been taken in the last several months to address youth use including raising the national minimum age of sale to 21 and restricting flavored e-cigarette sales to specific devices until other products receive approval from the FDA. These policies must be given a chance before further restricting products that have proven beneficial to adult smokers.

As noted in our previous letter, the primary consideration for the FDA in reviewing e-cigarette applications is the public health test. This means that manufacturers must demonstrate that marketing of the products would be appropriate for the protection of the public health. That standard requires the FDA to consider the risks and benefits to the population as a whole, including whether availability of the product will increase the likelihood that non-users will start using such products.[11]

In considering this this standard, the FDA has recognized the potential for flavors in some tobacco products to confer a public health benefit: "We recognize that the availability of alternatives to

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[6] "The Public Health Consequences of E-cigarettes," National Academies of Science, Engineering and Medicine, January 2018. pp. 617. http://nationalacademies.org/hmd/reports/2018/public-health-consequences-of-e-cigarettes.aspx.

[7] "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/Ecigarettes_a_firm_foundation_for_evidence_based_policy_and_practice.pdf

[8] 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

[9] 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.

[10] D. T. Levy et al., Examining the relationship of vaping to smoking initiation among US youth and young adults: a reality check, *Tob Control* (2018).

[11] 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). https://www.fda.gov/tobacco-products/rules-regulations-and-guidance/section-910-federal-food-drug-and-cosmetic-act-application-review-certain-tobacco-products.

traditional tobacco flavors in some products (*e.g.,* ENDS) may potentially help some adult users who are attempting to transition away from combusted products."[12] However, ultimate approval of individual flavors as a feature of some, or many, e-cigarettes can only happen if the FDA considers a specific flavor of a specific e-cigarette to meet the public health standard.

As such, we ask that the DC Council either table this proposal until the FDA has had a chance to review e-cigarette applications, or provide an exemption for products that are given approval for characterizing flavors.

When considering regulations aimed at reducing the burden of smoking, we strongly urge the District Council to consider the utility of harm reduction and reduced-risk products alongside prevention measures. It is imperative that access to e-cigarettes and vapor products remain at a level that encourages, rather than discourages, people to choose these less harmful products. Doing so will reduce the incidence and cost of tobacco-related disease.

Respectfully submitted,
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[12] Food and Drug Administration, 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, U.S. Department of Health and Human Services, May 10, 2016.
https://www.federalregister.gov/documents/2016/05/10/2016-10685/deeming-tobacco-products-to-be-subject-to-the-federal-food-drug-and-cosmetic-act-as-amended-by-the