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Testimony from:
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In OPPOSITION to MD Emergency Bill HB0003, “An Act Concerning Business Regulation – Flavored Tobacco Products – Prohibition.”

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About Us

The R Street Institute is a nonprofit, nonpartisan public policy research organization based out of Washington, D.C. We strive to promote free markets and effective government policies in many areas, including harm reduction.

My academic background is in the neural mechanisms of addiction, evaluating neurochemical and anatomical changes that happen in the brain following the onset of addiction. There has been a lot of progress made in understanding the biological factors that lead to dependence and addiction, and thus how addiction can best be treated and managed. However, no cessation or prevention program will be 100 percent successful—leaving many people behind. Toward that end, I believe that harm reduction approaches can positively affect the health and welfare of people who use addictive substances.

As the director of harm reduction policy, it is my ultimate goal to bring harm reduction approaches into equal standing as a third pillar of tobacco control, alongside demand reduction (increased cessation and prevention measures) and supply reduction (shifting to economies that do not rely on tobacco production). It is for this reason that I write to you out of concern over Emergency Bill HB0003, which seeks to prohibit the sale of flavored vapor products. From a public health perspective, it is important to incentivize people to use less harmful products, and allowing them to be available alongside combustible cigarettes will encourage people to avoid combustible cigarettes.

E-Cigarettes Are a Harm Reduction and Smoking Cessation Tool

Public Health England¹, the National Academies of Science, Engineering and Medicine² and the FDA³ have recognized that 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

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.”

unlikely to exceed 5 percent of the risk associated with combustible cigarettes.⁴ These products are recognized as presenting a reduced risk because they don't employ the traditional cigarette combustion process that releases 7,000 chemicals—some of which are highly carcinogenic. Former FDA Commissioner Scott Gottlieb has made reduced-risk products like e-cigarettes central to the FDA's roadmap:

While it's the addiction to nicotine that keeps people smoking, it's primarily the combustion, which releases thousands of harmful constituents into the body at dangerous levels, that kills people. This fact represents both the biggest challenge to curtailing cigarette addiction – and also holds the seeds of an opportunity that's a central construct for our actions. E-cigarettes may present an important opportunity for adult smokers to transition off combustible tobacco products and onto nicotine delivery products that may not have the same level of risks associated with them.⁵

In the spirit of this strategy, the first heat-not-burn product, IQOS, was granted marketing approval by the FDA on April 30, 2019.⁶ This marketing approval would not have been possible if this heat-not-burn product did not meet the rigorous standards set forth by the FDA, including being evaluated by the FDA as “appropriate for the protection of public health,”⁷ taking into account the risks and benefits to the population as a whole:

The statute provides that the basis for this finding shall be determined:

with respect to the risks and benefits to the population as a whole, including users and nonusers of the tobacco product, and taking into account –

(A) the increased or decreased likelihood that existing users of tobacco products will stop using such products; and

(B) the increased or decreased likelihood that those who do not use tobacco products will start using such products.

It is important to note that this standard will be the same when reviewing e-cigarette applications starting May 2020. All vapor products must submit an application by May 2020 or face removal from the market.

Although there are a number of pharmaceutical products that can help smokers quit, their low success rates necessitate that the public health community consider expanding the armamentarium to include electronic nicotine delivery systems (ENDS).

Indeed, e-cigarettes have quickly become the number one quit tool in many parts of the world, helping an untold number of smokers quit cigarettes. Public health modeling suggests 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

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 Scott Gottlieb, M.D., on new steps to address epidemic of youth e-cigarette use, “Statement from FDA Commissioner,” U.S. Food and Drug Administration, 2018. <https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm620185.htm>.

⁶ “FDA permits sale of IQOS Tobacco Heating System through premarket tobacco product application pathway,” April 30, 2019. <https://www.fda.gov/news-events/press-announcements/fda-permits-sale-iqos-tobacco-heating-system-through-premarket-tobacco-product-application-pathway>.

⁷ 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).

replacement therapies and counseling)⁸ and demonstrate a higher degree of success.⁹ Furthermore, 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.¹⁰

Flavors Help Smokers Transition Away from Combustible Cigarettes

The availability of non-tobacco flavors also assists smokers with the transition from combustible cigarettes. The International Journal of Environmental Research and Public Health reports that limitations in flavor choices negatively impact user experience. About 40 percent of e-cigarette-using, former and current adult smokers predict that removing their ability to choose flavors would make them less likely to remain abstinent or attempt to quit.¹¹ In fact, data suggests that current smokers are partial to the flavor of traditional tobacco, while fruit and sweet flavors are preferred by former smokers.

Moreover, it has recently been demonstrated that e-cigarette users who use non-tobacco flavors, including menthol and non-menthol (fruit, sweet, dessert) flavors are more likely to completely switch from combustible cigarettes than those who choose tobacco flavors.¹² Flavored e-liquids are yet another way that e-cigarettes can help smokers disassociate combustible cigarettes—and their characteristic flavor—from their pleasurable effects.

As you consider signing HB0003 into law, we strongly urge you to examine the utility of flavored vapor products as harm reduction tools that compliment traditional prevention measures. It is imperative that a range of e-cigarettes and vapor products remain accessible at a level that encourages, rather than discourages, smokers to choose these less harmful products. Doing so will reduce the incidence and cost of tobacco-related diseases.

Respectfully submitted,

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⁸ Health & Wellbeing Directorate, “E-cigarettes: a new foundation for evidence-based policy and practice,” Public Health England, August 2015.

https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/454517/E-cigarettes_a_firm_foundation_for_evidence_based_policy_and_practice.pdf.

⁹ 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>.

¹⁰ 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.

¹¹ Konstantinos E. Farsalinos et al., “Impact of flavour variability on electronic cigarette use experience: an internet survey,” *Int J Environ Res Public Health* 10:12 (2013), pp. 7272-82. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3881166/>.

¹² Christopher Russell et al., “Changing patterns of first e-cigarette flavor used and current flavors used by 20,836 adult frequent e-cigarette users in the USA,” *Harm Reduction Journal* 15:33 (2018). <https://harmreductionjournal.biomedcentral.com/articles/10.1186/s12954-018-0238-6#Abs1>.