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Testimony from:  
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In OPPOSITION to HB 5020, “AN ACT IMPLEMENTING THE GOVERNOR’S BUDGET RECOMMENDATIONS REGARDING PUBLIC HEALTH.”

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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 epidemiology, the study of how diseases and health outcomes are distributed throughout the population and how to apply this information to public health problems. Over the past several decades, public health has made great strides in decreasing smoking initiation and promoting smoking cessation. However, no cessation or prevention program is 100 percent successful—many people are left behind. To that end, I believe that harm reduction approaches can positively affect the health and welfare of people who use addictive substances, including nicotine.

The R Street Institute’s ultimate goal is 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). From a public health perspective, it is important to incentivize people to use less harmful products. Allowing their availability alongside combustible cigarettes will encourage people to choose alternatives to combustible cigarettes.

### **E-Cigarettes Are a Harm Reduction and Smoking Cessation Tool**

Public Health England<sup>1</sup>; the National Academies of Science, Engineering and Medicine<sup>2</sup>; and the FDA<sup>3</sup> 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

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<sup>1</sup> 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>.

<sup>2</sup> “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.”

<sup>3</sup> 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.”

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.<sup>4</sup> These products are recognized as presenting a reduced risk because they do not employ the traditional cigarette combustion process that releases around 7,000 chemicals—some of which are highly carcinogenic. In fact, former FDA commissioner Scott Gottlieb 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.<sup>5</sup>

Indeed, 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 suggests that e-cigarettes are contributing to more rapid declines in smoking rates than were seen in previous years. In the United States and United Kingdom e-cigarettes have outpaced traditional quit methods (varenicline, nicotine replacement therapies and counseling)<sup>6</sup> and demonstrate a higher degree of success.<sup>7</sup> 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.<sup>8</sup>

### **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 on 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.<sup>9</sup> In fact, data suggests that current smokers are partial to the flavor of traditional tobacco, while former smokers begin to prefer fruit and sweet flavors as they achieve abstinence from combustible cigarettes.

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

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<sup>4</sup> 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>.

<sup>5</sup> 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>

<sup>6</sup> “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](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)

<sup>7</sup> 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>

<sup>8</sup> 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.

<sup>9</sup> 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/>.

from combustible cigarettes than those who choose tobacco flavors.<sup>10</sup> Flavored e-liquids are yet another way that e-cigarettes can help smokers disassociate combustible cigarettes—and their characteristic flavor—from their pleasurable effects.

### **Nicotine Concentration**

One important consideration for the ability of nicotine to be a viable substitute for combustible cigarettes is that the nicotine concentration in an e-cigarette must mimic that of combustible cigarettes.

We oppose Section 2 (b) (1) proposing a maximum nicotine concentration of 35 mg/ml or 3.5 percent for alternative nicotine delivery systems, as this is likely to discourage some smokers from transitioning from combustible cigarettes.<sup>11</sup> In their article assessing nicotine absorption from e-cigarettes, Farsalinos et al. state, “Nicotine delivery to the bloodstream is important in determining the addictiveness of ECs, but also their efficacy as smoking substitutes.”<sup>12</sup> They also find that e-liquids with a nicotine concentration of approximately 50 mg/ml are necessary to deliver nicotine in a similar profile to combustible cigarettes.

The ability to achieve a similar nicotine delivery profile to that of combustible cigarettes is likely one reason that e-cigarettes are more effective cessation devices than pharmaceutical nicotine replacement therapy treatments.<sup>13</sup> During daily smoking, typical peak blood nicotine concentrations range from 19 to 50 ng/ml, while typical trough concentrations range from 10 to 37 ng/ml; depending on how the cigarette is smoked, each cigarette increases blood nicotine concentrations by 5–30 ng/ml.<sup>14</sup> By contrast, unrestricted use of nicotine replacement therapy products generally achieves only one to two thirds the blood nicotine concentrations achieved from combustible cigarettes.<sup>15</sup> For an individual with high nicotine dependence, the ability to more accurately duplicate the nicotine delivery profile of combustible cigarettes with e-cigarettes may be what makes their quit attempt succeed when previous attempts failed.

Farsalinos et al. found that 20 percent of e-cigarette users initiated use with e-liquids that contained nicotine concentrations greater than 20 mg/ml and nearly a quarter used nicotine concentrations greater than 20 mg/ml at the time they stopped using combustible cigarettes.<sup>16</sup> They also found that only 19 percent of e-cigarette users were able to completely switch from combustible cigarettes while using e-liquids with nicotine concentrations between 6 and 10 mg/ml. These results suggest that increasing the availability of e-liquids with nicotine concentrations greater than 20 mg/ml may assist smokers who have not quit with the products currently available.

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<sup>10</sup> 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>.

<sup>11</sup> European Commission. “E-cigarette Myth Buster.”

[https://ec.europa.eu/health/sites/health/files/tobacco/docs/tobacco\\_mythbuster\\_en.pdf](https://ec.europa.eu/health/sites/health/files/tobacco/docs/tobacco_mythbuster_en.pdf)

<sup>12</sup> Konstantinos Farsalinos et al. “Nicotine absorption from electronic cigarette use: comparison between first and new-generation devices.” *Scientific Reports*. 4:4133 (2014). <https://www.ncbi.nlm.nih.gov/pubmed/24569565/>

<sup>13</sup> 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. <https://www.nejm.org/doi/full/10.1056/NEJMoa1808779>

<sup>14</sup> Neal L. Benowitz et al. “Nicotine Chemistry, Metabolism, Kinetics and Biomarkers.” *Handbook of Experimental Pharmacology*. 192 (2009) pp. 29-60. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2953858/>

<sup>15</sup> Ibid.

<sup>16</sup> Konstantinos Farsalinos et al. “Evaluating Nicotine Levels Selection and Patterns of Electronic Cigarette Use in a Group of ‘Vapers’ Who Had Achieved Complete Substitution of Smoking.” *Substance Abuse*. 7 (2013) pp. 139-146. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3772898/>

It cannot be emphasized enough that for those who are unable to quit without assistance, chances for a successful, long-term transition away from combustible cigarettes will increase if alternative products are able to deliver nicotine in a similar fashion to that of combustible products.

When considering regulations aimed at reducing the burden of smoking, we strongly urge policymakers 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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