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Testimony from:
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In OPPOSITION to House Bill 1185, "A BILL to amend and reenact Section 18.2-371.2 of the Code of Virginia, relating to sale of nicotine vapor products; penalties"

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About Us

The R Street Institute is a nonprofit, nonpartisan public policy research organization based in 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 what biological factors 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—many people are left 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). From a public health perspective, it is important to incentivize people to use less-harmful products, and allowing their availability alongside combustible cigarettes will encourage people to not choose combustible cigarettes.

E-Cigarettes Are a Harm Reduction and Smoking Cessation Tool

Public Health England;[1] the National Academies of Science, Engineering and Medicine;[2] and the FDA[3] have recognized that nicotine products exist on a continuum of risk, with e-cigarettes

[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.

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 has stated that e-cigarettes are 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.[5]

Indeed, e-cigarettes have quickly become the number one quit tool in many parts of the world, helping countless smokers 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)[6] and demonstrate a higher degree of success.[7] 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.[8]

Nicotine Concentration and Additives

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

We oppose Section 18.2-371.2 (D) proposing a maximum nicotine concentration of 30 mg/ml or 3 percent for alternative nicotine delivery systems as this is likely to discourage some smokers

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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] 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] "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.

[7] 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.

[8] 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.

from transitioning off of combustible cigarettes.[9] In their article assessing nicotine absorption from e-cigarettes, Dr. Konstantinos Farsalinos et al. state that "Nicotine delivery to the bloodstream is important in determining the addictiveness of ECs, but also their efficacy as smoking substitutes."[10] 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.[11] 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 to 30 ng/ml.[12] By contrast, unrestricted use of nicotine replacement therapy products generally achieves only one- to two-thirds the blood nicotine concentration achieved from combustible cigarettes.[13] 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.

We also oppose the Section 18.2-371.2 (F) banning additives such as benzoic acid. As previously stated, one key aspect of the utility of e-cigarettes in transitioning away from combustible products is their ability to closely match nicotine distribution in the body.

Nicotine exists at a pH that makes this process inefficient. However, when combined with combustion, nicotine becomes more acidic and thus better able to distribute itself throughout the body. In an e-cigarette, a similar concentration of nicotine results in approximately 70 percent less exposure than that of combustible cigarettes.[14] Interestingly, as the concentration of nicotine—and thus the pH of the solution—in e-cigarettes increases, this distribution becomes less effective.

Combined with a salt formulation, such as benzoic acid or nicotine lactate, the nicotine solution can be lowered to a pH that allows for better distribution at lower concentrations. Although there is no evidence that nicotine in any currently marketed e-cigarette can reach the plasma concentrations of combustible products, distribution does increase to approximately 77 percent of that of combustible cigarettes at the highest concentrations available (48-50mg/ml).[15]

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[9] European Commission, "E-cigarette Myth Buster." https://ec.europa.eu/health/sites/health/files/tobacco/docs/tobacco_mythbuster_en.pdf.

[10] 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/.

[11] 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.

[12] 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/.

[13] Ibid.

[14] Grant O'Connell et al., "A randomised, open-label, cross-over clinical study to evaluate the pharmacokinetic profles of cigarettes and e-cigarettes with nicotine salt formulations in US adult smokers," *Internal and Emergency Medicine.* 14 (2019) pp. 853-861. https://link.springer.com/article/10.1007/s11739-019-02025-3.

[15] Peter Hajek et al., "Nicotine delivery to users from cigarettes and from different types of e-cigarettes," *Psychopharmacology* 234 (2017) pp. 773–779. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5306435/.

Since smokers are accustomed to their body's response to the nicotine delivery profile of combustible cigarettes, it follows that an alternative product should be able to achieve similar effects, at least while users make their initial transition. In fact, research indicates that higher nicotine concentrations help smokers make the initial switch from combustible cigarettes. This is one aspect of e-cigarettes that makes them an ideal cessation tool. They can achieve nicotine delivery similar to combustible cigarettes, and the concentration can be decreased gradually based on the user's needs and desires.[16]
It cannot be emphasized enough that for those who are unable to quit without assistance, the 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 remains at a level that encourages, rather than discourages, people to choose these less harmful products over combustible cigarettes. Doing so will reduce the incidence and cost of tobacco-related disease.

Respectfully submitted,

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[16] 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/.