



1212 New York Ave. N.W.  
Suite 900  
Washington, D.C. 20005  
202-525-5717

*Free Markets. Real Solutions.*  
*[www.rstreet.org](http://www.rstreet.org)*

Testimony from:  
Chelsea Boyd, Research Fellow for Harm Reduction Policy, R Street Institute

In OPPOSITION to Rule 37-923, “Pertaining to flavored electronic smoking devices.”

July 24, 2020

### **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 limited, 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 to decrease smoking initiation and promote smoking cessation. However, no cessation or prevention program is 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, including nicotine.

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). It is for this reason that I write to you out of concern over rule 37-923, 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; allowing their availability alongside combustible cigarettes will encourage people to choose alternatives.

## **E-Cigarettes are a harm reduction and smoking cessation tool**

Public Health England,<sup>1</sup> The Royal College of Physicians,<sup>2</sup> The National Academies of Science, Engineering and Medicine<sup>3</sup> and the FDA<sup>4</sup> 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, The Royal College of Physicians has stated that e-cigarettes are unlikely to exceed 5 percent of the risk associated with combustible cigarettes.<sup>5</sup> These products are recognized as presenting a reduced risk because they do not employ the traditional cigarette combustion process that releases more than 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.<sup>6</sup>

In the spirit of this strategy, the first heat-not-burn product, IQOS, was granted marketing approval by the FDA on April 30, 2019, and modified risk designation on July 7, 2020.<sup>7</sup> These marketing approvals would not have been possible if this heat-not-burn product did not meet the rigorous standards set

---

<sup>1</sup> Ann McNeill et al., “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](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).

<sup>2</sup> See, e.g., Tobacco Advisory Group, *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>3</sup> See, e.g., “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>.

<sup>4</sup> Scott Gottlieb, M.D., “FDA announces comprehensive regulatory plan to shift trajectory of tobacco-related disease, death,” Press Release, 2018.

<https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm568923.htm>.

<sup>5</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>6</sup> Scott Gottlieb, M.D., “Statement from FDA Commissioner Scott Gottlieb, M.D., on new steps to address epidemic of youth e-cigarette use,” Press Release, 2018.

<https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm620185.htm>.

<sup>7</sup> See, e.g., “FDA permits sale of IQOS Tobacco Heating System through premarket tobacco product application pathway,” Press Release, April 30, 2019. <https://www.fda.gov/news-events/press-announcements/fda-permits-sale-iqos-tobacco-heating-system-through-premarket-tobacco-product-application-pathway>; “FDA Authorizes Marketing of IQOS Tobacco Heating System with ‘Reduced Exposure’ Information,” Press Release, July 7, 2020. <https://www.fda.gov/news-events/press-announcements/fda-authorizes-marketing-iqos-tobacco-heating-system-reduced-exposure-information>.

forth by the FDA, including being evaluated by the FDA as “appropriate for the protection of public health,” 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.<sup>8</sup>

It is important to note that this standard will be the same when reviewing e-cigarette applications starting September 2020. All vapor products must submit an application by September 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 toolbox 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. 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 replacement therapies and counseling)<sup>9</sup> and demonstrate a higher degree of success.<sup>10</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>11</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 in flavor choices negatively impact user experience.<sup>12</sup> About 40 percent of e-cigarette-using, former and current adult smokers predict that removing their ability to choose flavors would make them

---

<sup>8</sup> U.S. Food and Drug Administration, “Section 910 of the Federal Food, Drug, and Cosmetic Act - Application for Review of Certain Tobacco Products,” U.S. Dept. of Health and Human Services, last accessed July 24, 2020, 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>.

<sup>9</sup> Health and 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](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).

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

less likely to remain abstinent or attempt to quit.<sup>13</sup> 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.<sup>14</sup>

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.<sup>15</sup> Flavored e-liquids are yet another way that e-cigarettes can help smokers disassociate combustible cigarettes—and their characteristic flavor—from the pleasurable effects of nicotine.<sup>16</sup>

As you consider rule 37-923, 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, vapor and heat-not-burn 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,

Chelsea Boyd, MS  
*Harm Reduction Policy Research Fellow*

---

<sup>13</sup> Ibid.

<sup>14</sup> Ibid.

<sup>15</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>16</sup> Ibid.