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Dear Speaker Pelosi, Minority Leader McCarthy and Members of the House of Representatives,

The R Street Institute – a nonprofit, nonpartisan public policy research organization focused on pragmatic solutions to policy challenges – has a number of concerns with H.R. 2339, the "Reversing the Youth Tobacco Epidemic Act of 2019." We recognize that preventing non-smoking young people from establishing both e-cigarette and combustible cigarette use is vital to the future health of the population. However, it is important to recognize that smoking is the leading cause of preventable death in the United States, and we must continually evaluate the available strategies for decreasing tobacco-related morbidity and mortality. E-cigarettes provide such a strategy.

Undoubtedly, the youth use trend is cause for concern and continued investigation. However, this cannot be the only measure of the effect of e-cigarettes on population health. Based on the body of research as a whole, we urge the committee to consider pursuing policies that reflect the short- and long-term population health impact of e-cigarettes relative to the known harms of combustible cigarettes.

E-cigarettes are a harm reduction and smoking cessation tool

The best available science indicates e-cigarettes are not likely to exceed 5 percent of the harm associated with combustible cigarettes, a conclusion supported by both Public Health England[1] and recently the National Academies of Sciences, Engineering and Medicine.[2] Also, like traditional nicotine replacement therapies, e-cigarettes do not produce environmental tobacco smoke that harms bystanders. It is estimated that e-cigarettes have the potential to save up to 6 million lives by 2100 if only 10 percent of current smokers switch to e-cigarettes in the next 10 years.

Many experts recognize that e-cigarettes present 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. For this reason, one such expert, 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

[1] "Nicotine without smoke: tobacco harm reduction," Royal College of Physicians Tobacco Advisory Group, 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.

may present an important opportunity for adult smokers to transition off combustible tobacco products.[3]

Although there are a number of pharmaceutical products that can help smokers quit, it is important to remember that it is not only nicotine dependence that makes quitting combustible cigarettes difficult. For some, smoking offers stress relief, comradery or other psycho-social pleasure, and some even consider it a component of their identity. This often makes the physical act of smoking just as difficult to quit as the nicotine. Unlike the FDA-approved methods of smoking cessation, e-cigarettes do not force a smoker to forgo the secondary pleasure they get from the act of smoking while they are adjusting to the physiological effects of decreased nicotine.

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 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)[4] and demonstrate a higher degree of success.[5] 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.[6]

Flavors help smokers transition away from combustible cigarettes

The availability of non-tobacco flavors also assists smokers with the transition away 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 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.[7] 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, indicating a correlation between flavors and sustained 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 from combustible cigarettes than those who choose tobacco flavors.[8] Flavored e-liquids are yet another way that e-cigarettes can help smokers disassociate combustible cigarettes—and the characteristic flavor—from their pleasurable effects.

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[3] 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.

[4] "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.

[5] 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

[6] 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.

[7] 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 (2013), pp. 7272-82.

[8] 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)

Although many organizations and leaders suggest flavors attract young people to e-cigarettes, the 2019 National Youth Tobacco Survey casts doubt on that assertion.[9] Among middle school and high school students, the most commonly endorsed reason for using e-cigarettes was "I was curious about them." Overall, 53 percent of students surveyed indicated curiosity as a reason they use e-cigarettes.[10] The second most common reason for use was if a student's friend or family member used e-cigarettes.[11] With just 22 percent of students endorsing availability of flavors as a reason for vaping, it is clear that social factors, not flavors, are the driving force behind youth e-cigarette use.[12]

R Street applauds raising the age of purchase of all tobacco products to 21

Of course, smokers are not the only population impacted by e-cigarettes, and addressing youth use is important. Our organization, the R Street Institute, endorsed raising the minimum age of purchase for all tobacco products to 21, which was signed into law Dec. 20, 2019. This change will help prevent youth access in high school by limiting opportunities for younger students to buy from peers who, prior to the federal minimum-age-to-purchase increase, obtained the products legally. In combination with more stringent point-of-sale age verification and meaningful penalties for merchants who violate minimum-age-to-purchase laws, this change will significantly limit youth access.

The impact of nationwide 21-to-purchase legislation is yet to be evaluated; however, evidence from areas that raised the minimum age to purchase prior to the federal legislation suggests that this change will be highly effective at decreasing youth tobacco use. Following implementation of a 21-to-purchase law in Needham, Massachusetts, there was an unprecedented 47 percent reduction (from 13 to 7 percent) in past 30-day smoking rates among high schoolers over four years (2008-2012).[13]

R Street does not support banning non-face-to-face sales of e-cigarettes

It is imperative that the availability of reduced-risk alternatives remains in place for people who use e-cigarettes as a cessation tool. According to the 2016 Surgeon General's Report,[14] in 2014, 20 percent of all e-cigarette sales occurred online. It is estimated that in 2018, 32 percent of all e-cigarette sales occurred online.[15] As more proposals arise to limit what kinds of brick and mortar establishments are able to sell e-cigarettes or other reduced-risk products—all while protecting combustible sales—online sales may be the only point of access for people who, for many reasons, cannot reach specialty stores. It should not be a surprise to the committee that people who live with disabilities, are economically disadvantaged or live in rural areas are overrepresented in the smoking population. These particular

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[9] Teresa W. Wang et al., "Tobacco Product Use and Associated Factors Among Middle and High School Students — United States, 2019," Centers for Disease Control Morbidity and Mortality Weekly Report, 68:12 (Dec. 6, 2019) pp. 1-22. https://www.cdc.gov/mmwr/volumes/68/ss/ss6812a1.htm.

[10] Ibid.

[11] Ibid.

[12] Ibid.

[13] Shari Kessel Schneider et al., "Community reductions in youth smoking after raising the minimum tobacco sales age to 21," *Tobacco Control* 25 (2015), pp. 355-59.

[14] Office of Smoking and Health, "E-Cigarette Use Among Youth and Young Adults: A Report of the Surgeon General," U.S. Department of Health and Human Services, December 2016. https://e-cigarettes.surgeongeneral.gov/documents/2016_sgr_full_report_non-508.pdf.

[15] "E-cigarettes: Facts, stats and regulations," The Truth Initiative, July 19, 2018. https://truthinitiative.org/research-resources/emerging-tobacco-products/e-cigarettes-facts-stats-and-regulations

factors represent true barriers to face-to-face access to specialty products. Online sales and delivery may be the only way that smokers have access to safer products.

Furthermore, there is a misperception that online sales of e-cigarettes are more vulnerable to underage access. Legal retailers that sell their products online have strict FDA-mandated age verification systems that are successful in preventing underage access to their products. Unverified underage sales largely occur on eBay or other websites where age verification is not vital. Banning non-face-to-face sales will not stop illegitimate online sales to underage persons from occurring, as these sales are already illegal.

The FDA's role in protecting public health

Finally, it is important to recognize that the FDA has developed a regulatory pathway to evaluate the safety and public health impact of all new tobacco products, including considerations of flavors. This is a process that has been carefully designed over several years to ensure new tobacco products, like e-cigarettes, will not have a negative impact on the health of the population as a whole. Given that manufacturers must file their Premarket Tobacco Applications for all deemed tobacco products, which includes virtually all e-cigarettes, by May 12, 2020 or risk removal from the market, it makes sense to delay enacting any federal bans.[16] Allowing the safety and regulatory experts at the FDA to lead the way in authorizing the sale of these products is the most appropriate way forward, something acknowledged by §103(d.2) of this bill.[17]

Policies that treat e-cigarettes the same as combustible cigarettes encourage current smokers to continue doing enormous harm to their health by discouraging a switch from combustible products. Conversely, policies that reflect the lesser harm of e-cigarettes can significantly reduce the enormous burden of disease that combustible cigarettes impose on society.

One thing is certain: We are all striving to improve and protect the nation's health. To do so, we must recognize the potential for e-cigarettes to mitigate risks associated with combustible cigarettes if we wish to encourage a healthful populace. We encourage you to consider policies that reflect the reduced risk of e-cigarettes compared to combustible cigarettes as we work towards creating a healthier population.

Thank you for your time and consideration.

Respectfully submitted,

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[16] Troutman Sanders Tobacco Practice, "Vapor Company Appeals Dismissal of Challenge to PMTA Deadline," Tobacco Law Blog, Feb., 18, 2020. https://www.tobaccolawblog.com/2020/02/vapor-company-appeals-dismissal-of-challenge-to-pmta-deadline/#more-3865

[17] Reversing the Youth Tobacco Epidemic Act of 2019, H.R. 2339, 116th Cong. https://www.congress.gov/bill/116th-congress/house-bill/2339/text. Accessed Feb. 19, 2020.