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BANNING FLAVORED E-CIGARETTES COULD HAVE UNINTENDED PUBLIC HEALTH CONSEQUENCES

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EXECUTIVE SUMMARY

Since their introduction to U.S. consumers in 2007, Electronic Nicotine Delivery Systems (ENDS or e-cigarettes) have gained popularity across age groups. However, as vaping prevalence grew among teens and young adults, public health experts warned against the risk of addiction and potential damage that nicotine use poses to developing brains. This, in turn, has prompted a flurry of policies at local, state and national levels that target the wide variety of flavored nicotine products believed to appeal directly to underage consumers.

The specific policies are too recent and too uneven to evaluate directly. However, a review of the research on e-cigarettes as smoking cessation tools, the appeal of flavors and the impacts of other tobacco legislation suggest that flavor bans will likely have both public health benefits and consequences. Two potential consequence stand out: unintended harms to consumers through the disruption of smoking cessation efforts and the growth of counterfeit and contraband products; and harm to communities via lost funding for broader health resources.

A limited number of studies have looked at people's actual and presumptive responses to flavor bans. This small body of research suggests that the policy could reduce vaping in general, but that it may drive some current vapers to resume or increase their use of combustible cigarettes and others to seek out their preferred e-cigarette flavors through illicit markets and hard-to-regulate online retailers. As such, both potential sets of behavior changes could tip the net public health impact of flavor bans toward harmful.

Because ENDS users inhale a nicotine-infused vapor rather than toxin-laden tobacco smoke, vaping is considered a safer alternative to smoking combustible cigarettes. In fact, both the U.S. Centers for Disease and Prevention and Public Health England have stated (albeit to varying degrees) that smokers would benefit from switching to e-cigarettes, and the devices are gaining traction as cessation tools. Furthermore, research shows that flavors may aid individuals who are using e-cigarettes to quit or reduce smoking. Flavor bans, as a result, risk diminishing ENDS products' role in harm reduction.

A small but consistent proportion of vapers who opt to continue using flavored e-cigarettes after a ban may face a different type of health risk. The tobacco market is considered especially vulnerable to counterfeit and contraband products, both of which are more likely to be more dangerous than their legal counterparts. Counterfeit e-cigarettes have been found to be mislabeled, have high levels of potential toxins, and poor manufacturing standards. Scholars who have studied prohibition of tobacco and other drugs posit that increased restriction often leads to a rise in the prevalence of illicit products and markets.

Beyond the potential unintended consequences that prohibitions have for current or future vapers, flavor bans could affect communities more widely. State and federal governments do apply a proportion of tobacco tax revenue to prevention and cessation resources. However, much of that

money is used for programs that serve the general public, such as the national Children's Health Insurance Program or Colorado's enhanced health care funding for low-income older adults. Because e-cigarettes are believed to be associated with few health consequences, these funds come at relatively low cost. Thus, reducing such revenue while driving new public health challenges could be harmful to communities as a whole.

It is not yet clear exactly how bans on flavored e-cigarettes will play out. However, by extrapolating from the limited studies available as well as research on e-cigarettes and tobacco policy more generally, it appears that the outcomes will be mixed and complex. As such, it is important for policy makers and community members considering such prohibitions to weigh the potential for public health consequences as well as possible benefits.

INTRODUCTION

When Hon Lik patented his first electronic cigarette (e-cigarette) in 2003, he was not looking to disrupt Big Tobacco or create a public health controversy.[1] Rather, he hoped that by simulating the experience of smoking while leaving out the hazards of tobacco, he could give combustible cigarette users a tool that would help them quit.[2] Today, the devices, also known as Electronic Nicotine Delivery Systems (ENDS), come in a variety of shapes and sizes and generally work by heating a liquid—infused with nicotine (or other substance)—to produce an aerosol that consumers inhale. The vast majority are battery-operated; some are reusable, with separate cartridges and rechargeable batteries, and others are self-contained, disposable units. Flavors such as fruit, candy, menthol and tobacco come preloaded or can be purchased as separate additives. As of 2019, e-cigarettes constituted a nearly $12 billion annual market that is expected to climb to more than $21 billion by 2023.[3] And according to the National Center for Health Statistics, in 2018, 14.9 percent of U.S. adults reported ever having used an e-cigarette, while 3.2 percent were current users.[4]

Since ENDS products came onto the U.S. market in the mid-aughts, their growing popularity among teens and young adults has raised red flags for public health experts and policy makers alike.[5] In particular, agencies such as the Centers for Disease Control and Prevention (CDC) have expressed concern that non-tobacco flavors, especially those that mimic fruit and candy, appeal disproportionately to underage consumers.[6] Since most e-cigarettes on the market contain nicotine, experts worry that, even though ENDS products offer safer delivery than combustible cigarettes, using them places developing brains at risk and fosters addiction in a new generation of individuals who could eventually transition to combustible cigarettes.[7]

In response to these concerns, the Food and Drug Administration (FDA) issued a nationwide ban on flavors other than tobacco or menthol in cartridge-based e-cigarettes until manufacturers were able to demonstrate that the flavors are "appropriate for the protection of public health."[8] As of this writing, dozens of municipal and county governments as well as two states—California and Massachusetts—have taken matters further, seeking to prohibit flavored ENDS products, albeit unevenly. Such policies vary in their target, with some focusing exclusively on the cartridges used in rechargeable ENDS and others including self-contained disposable vaping products as well as flavored tobacco.[9]

Attempts at restricting access to flavored ENDS products have been met with a fair amount of pushback. In a survey of San Francisco tobacco users, only 8.1 percent of participants supported the flavor ban.[10] California's law, passed in August 2020, has been challenged in the courts and is now on hold

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Note: This is a corrected version of the paper originally published. Two edits have been made to correct factual errors.

1. Barbara Demick, "A high-tech approach to getting a nicotine fix," *Los Angeles Times*, April 25, 2009. https://www.latimes.com/archives/la-xpm-2009-apr-25-fg-china-cigarettes25-story.html.

2. Martinne Geller, "E-cigs a 'consumer-driven' revolution born from a bad dream," *Reuters*, June 9, 2015. https://www.reuters.com/article/us-ecigarettes-inventor/e-cigs-a-consumer-driven-revolution-born-from-a-bad-dream-idUSKBN0O-P1YV20150609.

3. "E-Cigarettes Market Worth $21.4 billion by 2023 - Increasing Number of M&A's Between Traditional Cigarette and E-Cigarette Manufacturers," *Globe Newswire*, Feb. 10, 2020. https://www.globenewswire.com/news-release/2020/02/10/1982130/0/en/E-Cigarettes-Market-Worth-21-4-billion-by-2023-Increasing-Number-of-M-A-s-Between-Traditional-Cigarette-and-E-Cigarette-Manufacturers.html.

4. Maria A. Villarroel, et al., "Electronic Cigarette Use Among U.S. Adults, 2018," *NCHS Data Brief*, No. 365, Centers for Disease Control, U.S. Department of Health and Human Services, April 2020. https://www.cdc.gov/nchs/data/databriefs/db365-h.pdf.

5. National Center for Chronic Disease Prevention and Health Promotion (U.S.) Office on Smoking and Health, "Activities of the E-Cigarette Companies," in *E-Cigarette Use Among Youth and Young Adults: A Report of the Surgeon General*, (Centers for Disease Control and Prevention, 2016), pp. 147-179. https://www.ncbi.nlm.nih.gov/books/NBK538680/pdf/Bookshelf_NBK538680.pdf; Jia Tolentino, "The promise of vaping and the rise of Juul," *The New Yorker*, May 14, 2018. https://www.newyorker.com/magazine/2018/05/14/the-promise-of-vaping-and-the-rise-of-juul.

6. Campaign for Tobacco-Free Kids, "E-Cigarettes: Flavored Products Fuel A Youth Epidemic," *Industry Watch*, last accessed Feb. 8, 2021. https://www.tobaccofreekids.org/what-we-do/industry-watch/e-cigarettes#:~:text=Flavored%20products%2C%20especially%20Juul%2C%20have,gummy%20bear%20and%20cotton%20candy

7. National Center for Chronic Disease Prevention and Health Promotion (U.S.) Office on Smoking and Health, "Health Effects of E-Cigarette Use Among U.S. Youth and Young Adults," in *E-Cigarette Use Among Youth and Young Adults: A Report of the Surgeon General*, (Centers for Disease Control and Prevention, 2016), pp. 95-146. https://www.ncbi.nlm.nih.gov/books/NBK538680/pdf/Bookshelf_NBK538680.pdf

8. U.S. Food and Drug Administration, *Enforcement Priorities for Electronic Nicotine Delivery System (ENDS) and Other Deemed Products on the Market Without Premarket Authorization (Revised)*, U.S. Department of Health and Human Services, April 2020. https://www.fda.gov/media/133880/download.

9. Public Health Law Center, U.S. *Restrictions on Flavored Tobacco Products*, Mitchell Hamline School of Law, April 2020. https://publichealthlawcenter.org/sites/default/files/resources/US-Sales-Restrictions-Flavored-Tobacco-Products-2018.pdf.

10. Yong Yang, et al., "The impact of a comprehensive tobacco product flavor ban in San Francisco among young adults," *Addictive Behaviors Reports*, 11 (June 2020). https://www.sciencedirect.com/science/article/pii/S2352853220300134.

until at least 2022.[11] Similarly, Colorado's potential legislation was challenged for its anticipated economic consequences.[12]

Given the recency and unevenness of ENDS flavor bans across the United States, there is currently insufficient research on the policies themselves to evaluate outright. However, studies on related topics indicate that such bans may come with unanticipated public health consequences. After considering the literature on the use of e-cigarettes in smoking cessation, the appeal of flavored e-cigarettes, the impacts of age and tax policies, and more, this paper highlights factors that policymakers should consider as they weigh the benefits and drawbacks of prohibiting flavored e-cigarettes in their cities and states. Two broad areas stand out: First, policies may directly cause a range of unintended harms to consumers, and second, they could indirectly result in the loss of funding for important programs that contribute to broader community well-being.

THE POTENTIAL FOR UNINTENDED HARMS

According to the CDC, combustible cigarettes are the world's leading cause of preventable death. Each year, an estimated seven million people die worldwide of diseases related to smoking or inhaling secondhand smoke. Almost 500,000 of those deaths are in the United States.[13] While there are public health concerns about the addictive capacity of ENDS products, it is important to recognize that the devices do not burn tobacco, and it is tobacco smoke, rather than nicotine, that is responsible for those deaths. Because of this distinction, e-cigarettes are widely accepted as having fewer health consequences than smoking combustible cigarettes.

Both clinical and laboratory studies have shown that e-cigarettes are far less harmful than combustible cigarettes, although the extent of this relative safety is difficult to quantify.[14] As recently as 2018, Public Health England estimated that ENDS products are 95 percent safer than combustible cigarettes.[15] But in the United States, where e-cigarette nicotine levels are substantially higher, experts have been reticent to put a number on that difference. Specifically, rather than comparing the relative safety of vaping and smoking, the CDC stresses that any nicotine or tobacco use is more harmful than no nicotine or tobacco use. Such an abstinence-only approach has been shown to be less effective at protecting health when compared to education and interventions rooted in a harm reduction ethos.[16] As such, the CDC does acknowledge that e-cigarettes are a safer alternative to their combustible counterparts, and suggests that smokers could benefit from switching to vaping.[17]

Thus, while one cannot say that vaping is entirely without risk, because ENDS products are deemed much safer than combustible cigarettes, they are increasingly accepted as a harm reduction tool. In fact, the United Kingdom has embraced the devices as part of their overall approach to tobacco control and promotes their use as smoking cessation aids.[18]

PREDICTING RESPONSE TO A FLAVOR BAN

To date, there is minimal research on how recently enacted e-cigarette flavor bans affect actual behavior. However, asking vapers to anticipate how they would respond to a flavor ban in their area highlights the possibility of product substitution as well as an increased willingness to access counterfeit and black-market products. Many ENDS users indicate that they would be likely to resume (or fail to quit) cigarette smoking, and others say that they would seek out products in uncontrolled markets. In one longitudinal study, for example, 50 percent of participants said they would "find a way" to access their preferred product; some even said they would add their own flavoring agents.[19] Furthermore, 9.7 percent of those surveyed indicated that they would simply go back to smoking combustible cigarettes.[20]

These predictions are consistent with the very limited data on actual behaviors when flavors are banned. We were able to identify only one peer-reviewed study of reported behaviors in the United States—a survey of 247 nicotine users aged 18 to 34 in San Francisco, conducted ten months after the

11. Jamie Long, "What the Referendum on California's Flavored Tobacco Sales Means," Blog, Public Health Law Center, Mitchell Hamline School of Law, Jan. 25, 2021. https://www.publichealthlawcenter.org/blogs/2020-09-04/what-referendum-californias-flavored-tobacco-sales-ban-means.

12. John Daley, "Proposed Ban on Flavored Nicotine and Tobacco Has a Money Problem," *Colorado Public Radio*, March 4, 2020. https://www.cpr.org/2020/03/04/proposed-ban-on-flavored-nicotine-and-tobacco-has-a-money-problem.

13. Nancy A. Rigotti, "Randomized Trials of e-Cigarettes for Smoking Cessation," *Journal of the American Medical Association* 324:18 (Nov. 10, 2020), pp. 1835-1837. https://jamanetwork.com/journals/jama/fullarticle/2772742.

14. Konstantinos E. Farsalinos and Riccardo Polosa, "Safety evaluation and risk assessment of electronic cigarettes as tobacco cigarette substitutes: a systematic review," *Therapeutic Advances in Drug Safety* 5:2 (2014), pp. 67-86. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4110871/pdf/10.1177_2042098614524430.pdf.

15. Sarah Boseley, "Public Health England maintains vaping is 95% less harmful than smoking," *The Guardian*, Dec. 28, 2018. https://www.theguardian.com/society/2018/dec/28/vaping-is-95-safer-than-smoking-claims-public-health-england.

16. Carl V. Phillips, "Debunking the claim that abstinence is usually healthier for smokers than switching to a low-risk alternative, and other observations about anti-tobacco-harm-reduction arguments," *Harm Reduction Journal* 6:29 (Nov. 3, 2009). https://www.theguardian.com/society/2018/dec/28/vaping-is-95-safer-than-smoking-claims-public-health-england.

17. "About Electronic Cigarettes (E-Cigarettes)," Centers for Disease Control and Prevention, 2020. https://www.cdc.gov/tobacco/basic_information/e-cigarettes/about-e-cigarettes.html.

18. Associated Press, "The UK is embracing e-cigarettes as an anti-smoking tool as the US cracks down on vaping," CNBC, Sept. 28, 2019. https://www.cnbc.com/2019/09/28/the-uk-is-embracing-e-cigarettes-as-an-anti-smoking-tool-as-the-us-cracks-down-on-vaping.html.

19. Ping Du et al., "Changes in Flavor Preference in a Cohort of Long-Term Electronic Cigarette Users," *Annals of the American Thoracic Society*, 17: 5 (May 2020), pp. 573-581. https://pubmed.ncbi.nlm.nih.gov/31978316.

20. Ibid.

city's January 2019 comprehensive prohibition of the sale of all non-tobacco flavored e-cigarettes. In response to San Francisco's flavor ban, nearly 21 percent of exclusive flavored e-cigarette users said they had quit all tobacco and nicotine use following the ban; however, only 4 percent of individuals who had used flavored e-cigarettes alongside other tobacco products prior to the ban gave up tobacco and nicotine completely. And while e-cigarette use declined, Yang et al. found an overall increase in cigarette smoking among 18 to 24-year-old participants. In addition, among those who did not quit nicotine altogether, some troubling patterns emerged. Of those who continued using the banned product, 15 percent shopped online, 5 percent made illegal purchases and 4.5 percent bought products from otherwise legal retailers that did not comply with the ban.[21]

Unfortunately, the authors note,[22] the above study was conducted in November of 2019, in the midst of an outbreak of vaping-related lung injuries and deaths that has since been linked to additives commonly found in cannabis and specific counterfeit e-cigarettes.[23] As a result, it is unclear whether overall declines in e-cigarette use can be attributed to the flavor ban or growing safety concerns linked to the outbreak.[24] This muddies findings about the most promising aspects of the ban.

A more recent nationwide industry survey of 1,016 e-cigarette consumers found similar trends. Eighty-six percent of those surveyed (877 individuals) reported that flavored ENDS products remain in their areas. Asked to predict their responses following a hypothetical ban, 13 percent said they would consume more combustible cigarettes and 11 percent said they would start using combustible cigarettes. A smaller group (112 individuals), for whom flavored ENDS products were unavailable, reflected on the ways they have adapted. Among these respondents, 23 percent said they purchased online, 4 percent said they increased combustible cigarette use, and 4 percent said they started using combustible cigarettes.[25]

These limited but compelling findings are further supported by looking more broadly at the literature on tobacco prohibition. Research on existing policies restricting and taxing tobacco and other drugs provide some insights. In particular, a robust body of evidence indicates that responses to tobacco prohibitions are often mixed such that gains in one area may be offset by losses in another. In many cases, this tradeoff may consist of a decrease in e-cigarette initiation but a reduction in the number of individuals who quit smoking.

In August 2016, following the vast majority of states, the FDA mandated a minimum legal sale age (MLSA) of 18 years for e-cigarettes. Early evidence suggests that such age restrictions do reduce e-cigarette use among youth, but they are also associated with an uptick in cigarette smoking. In fact, the authors of one study noted that the introduction of age restrictions on e-cigarettes "may have contributed to a little over half of the increase in smoking participation," especially among youth who had not smoked combustible cigarettes prior to the legislation.[26] In December 2019, the Trump administration amended the Federal Food, Drug and Cosmetic Act, raising the legal age to purchase any tobacco product, including e-cigarettes, to 21.[27] It is not yet clear what effect this will have on youth vaping.

Tax studies provide further support for concerns that while disrupting e-cigarette access may reduce vaping among some individuals, it can simultaneously lead others to increase or revert to smoking combustible cigarettes. For example, a 2011 to 2017 study of 35,000 retailers estimated that increasing taxes on ENDS products by 10 percent leads to a 13 percent reduction in e-cigarette sales while a 1 percent increase in the price of e-cigarettes boosts combustible cigarette sales by 0.8 percent.[28] Historically, policies restricting tobacco have also resulted in substitutions. For example, the FDA's 2009 ban on flavored cigarettes was followed by a 6 percent reduction in the likelihood of youth tobacco use. However, while probability of smoking cigarettes fell, use of menthol

21. Yang et al., 2020. https://www.sciencedirect.com/science/article/pii/S2352853220300134.

22. Ibid.

23. Matthew J. Lozier et al., "Update: Demographic, Report, and Substance-Use Characteristics of Hospitalized Patients in a Nationwide Outbreak of E-cigarette, or Vaping, Product Use—Associated Lung Injuries—United States, December 2019," *Morbidity and Mortality Weekly Report* 68:49, pp. 1142-1148, Dec. 13, 2019. https://www.cdc.gov/mmwr/volumes/68/wr/mm6849e1.htm; Livia Navon et al., "Risk Factors for E-Cigarette, or Vaping, Product Use-Associated Lung Injury (EVALI) Among Adults Who Use E-Cigarette, or Vaping, Products—Illinois, July-October 2019," *Morbidity and Mortality Weekly Report* 68:45, pp. 1034-1039, Nov. 15, 2019. https://www.cdc.gov/mmwr/volumes/68/wr/mm6845e1.htm; Benjamin C. Blount et al., "Vitamin E Acetate in Bronchoalveolar-Lavage Fluid Associated with EVALI," *New England Journal of Medicine* 382 (Feb. 20, 2020), pp. 697-705. https://www.nejm.org/doi/full/10.1056/NEJMoa1916433.

24. Harry Tattan-Birch et al., "Association of the US Outbreak of Vaping-Associated Lung Injury With Perceived Harm of e-Cigarettes Compared With Cigarettes," *Journal of the American Medical Association* 3:6 (June 15, 2020). https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2767134.

25. Disposable Vape User Insights (2021)," Technomic Inc., last accessed Feb. 24, 2021. https://wholesale.bidivapor.com/how-flavors-and-nicotine-percentage-may-affect-consumer-use.

26. Dhaval Dave et al., "The effects of e-cigarette minimum legal sale age laws on youth substance use," *Health Economics* 28 (March 2019), pp. 419-436. https://pubmed.ncbi.nlm.nih.gov/30648308.

27. "Tobacco 21," U.S. Food and Drug Administration, Feb. 2, 2020. https://www.fda.gov/tobacco-products/retail-sales-tobacco-products/tobacco-21.

28. Chad D. Cottie et al., "The Effects of E-Cigarette Taxes on E-Cigarette Prices and Tobacco Product Sales: Evidence From Retail Panel Data," *NBER Working Paper* No. 26724, National Bureau of Economic Research, January 2020/Revised August 2020. https://www.nber.org/system/files/working_papers/w26724/w26724.pdf.

cigarettes, cigars and pipes increased, diminishing benefits.[29]

The early findings that suggest flavor bans may lead to a rise in willingness among vapers to access their preferred product by turning to online and even illicit markets is upsetting, but not particularly surprising if we look at the history of prohibition. As one 2015 study explained:

> As stricter controls on cigarettes are implemented, basic economic analysis as well as historical evidence suggest that we should expect to see an expansion of tobacco smuggling, tax avoidance, and counterfeiting.[30]

For example, a 2020 report issued by Massachusetts' Multi-Agency Illegal Tobacco Task Force acknowledged that the Commonwealth's high tobacco taxes relative to surrounding states prompted smuggling and illicit resale markets.[31] In 2018, Massachusetts smokers purchased more than one-fifth of their cigarettes from out of state. In the months following the state's ban on flavored tobacco, while tobacco and nicotine purchases within Massachusetts declined, they stayed stable throughout the region, indicating smokers and vapers were simply crossing borders. In support of this conclusion, sales climbed, sometimes substantially, in Rhode Island, New Hampshire and other states throughout the Northeast.[32]

Impacts of a Flavor Ban on Harm Reduction

Quitting, or even cutting back on, smoking is a notoriously difficult endeavor. A majority of adult smokers—more than two-thirds (22.7 million) in 2015—report wanting to quit.[33] However, in a given year only about 7 percent succeed.[34] Indeed, harm reduction was Lik's intent when he developed his first e-cigarettes almost 20 years ago. As a heavy smoker whose father (also a smoker) died of lung cancer in 2004, he understood first-hand the risks associated with combustible cigarettes, as well as the challenge of reducing one's use. But, as he told *Reuters* in 2015, he deemed standard nicotine replacement therapies inadequate. For example, the steady stream of nicotine provided by the patch left him missing the relaxation and stress relief he had come to associate with the rush of a cigarette, and thus did little to quench his desire to smoke.[35]

In 2005, nearly 21 out of every 100 American adults was classifiable as a "current smoker." By 2019, that number had fallen to 14 of every 100 adults.[36] This absolute decline of seven percentage points amounts to a 33 percent reduction in the proportion of smokers. Some believe that this recent downward trend in cigarette use can be attributed in part to smokers' conversion to e-cigarettes. Approximately one quarter (25.2 percent) of current e-cigarette users and 57.3 percent of individuals who have ever vaped are adults who quit smoking combustible cigarettes within the past year.[37] Indeed, data from the Population Assessment of Tobacco and Health Study indicate that 6.9 percent of individuals who smoked cigarettes at the first survey had transitioned completely to e-cigarettes by the second, becoming former smokers. Individuals who reported using e-cigarettes daily during the second survey were 7.88 times more likely than non-users of e-cigarettes to have quit smoking for 30 days. And those who did not quit still had 5.70 times the odds of reducing their average daily cigarette use by at least 50 percent.[38]

A challenge to quantifying the role of ENDS products as smoking cessation tools is the relatively limited body of research. In particular, there is a dearth of large, high-quality, randomized clinical trials. Moreover, of these types of studies, few have been conducted in the United States due to FDA regulations.[39]

Recently, however, a number of systematic reviews have sought to provide an overview of findings from the extant research. One such review examined 50 studies—26 of which were randomized controlled trials—and a total of 12,430 participants.[40] Based on a meta-analysis of a subset of those studies, the authors estimate that nicotine-containing ENDS products, when used for the purpose of smoking cessation,

29. Charles J. Courtemanche et al., "Influence of the Flavored Cigarette Ban on Adolescent Tobacco Use," *American Journal of Preventive Medicine* 52:5 (May 2017), pp. e139-e146. https://pubmed.ncbi.nlm.nih.gov/28081999.

30. Jonathan Kulick et al., "Unintended consequences of cigarette prohibition, regulation, and taxation," *International Journal of Law, Crime and Justice* 46 (September 2016), pp. 69-85. https://www.sciencedirect.com/science/article/abs/pii/S1756061616300416.

31. Marikae Grace Toye et al., *Annual Report of Multi-Agency Illegal Tobacco Task Force*, Multi-Agency Illegal Tobacco Task Force of Massachusetts, Feb. 28, 2020. https://www.mass.gov/doc/task-force-fy20-annual-report/download.

32. Ulrik Boesen, "Massachusetts Flavored Tobacco Ban Has Severe Impact on Tax Revenue," Tax Foundation, Feb. 8, 2021. https://taxfoundation.org/massachusetts-flavored-tobacco-ban/#:~:text=Massachusetts%20collected%20%24557%20million%20in,revenue%20of%20roughly%20%2450%20million.

33. "Smoking Cessation: Fast Facts," Centers for Disease Control and Prevention, Feb. 6, 2021. https://www.cdc.gov/tobacco/data_statistics/fact_sheets/cessation/smoking-cessation-fast-facts/index.html.

34. "What you need to know to quit smoking," Truth Initiative, Nov. 7, 2018.https://truthinitiative.org/research-resources/quitting-smoking-vaping/what-you-need-know-quit-smoking#:~:text=We%20give%20young%20people%20the,a%20thing%20of%20the%20past..

35. Geller, 2015. https://www.reuters.com/article/us-ecigarettes-inventor/e-cigs-a-consumer-driven-revolution-born-from-a-bad-dream-idUSKBN0OP1YV20150609.

36. "Current Cigarette Smoking Among Adults in the United States," Centers for Disease Control and Prevention, Dec. 10, 2020. https://www.cdc.gov/tobacco/data_statistics/fact_sheets/adult_data/cig_smoking/index.html.

37. Villarroel et al., 2020. https://www.cdc.gov/nchs/data/databriefs/db365-h.pdf.

38. Kaitlyn M. Berry et al., "E-cigarette initiation and associated changes in smoking cessation and reduction: The Population Assessment of Tobacco and Health Study, 2013-2015," *Tobacco Control* 28:1 (2019), pp. 42-49. https://tobaccocontrol.bmj.com/content/tobaccocontrol/28/1/42.full.pdf.

39. Rigotti, 2020, pp. 1835-1837. https://jamanetwork.com/journals/jama/fullarticle/2772742.

40. Jamie Hartmann-Boyce et al., "Electronic cigarettes for smoking cessation," *Cochrane Database of Systematic Reviews* 10 (Oct. 14, 2020). https://www.cochranelibrary.com/cdsr/doi/10.1002/14651858.CD010216.pub4/full

may lead to between four and six additional quitters per 100 compared to non-nicotine electronic cigarettes or nicotine replacement therapy (such as a nicotine patch). The relative benefits of ENDS products compared to alternatives held true for both randomized and non-randomized studies.

Another analysis—this one included 12 studies (including 8,362 participants) in a systematic review and nine in a meta-analysis—found that individuals who used nicotine e-cigarettes were 1.71 times more likely to quit smoking than those who used non-nicotine e-cigarettes and 1.69 times more likely to quit smoking compared to participants who received nicotine replacement therapy.[41] More recently, a prospective study compared quit rates and quit success among exclusive smokers, dual users of cigarettes and ENDS products, and dual users of cigarettes and nicotine replacement therapy (NRT) in England. They found that although ENDS users were less likely than NRT users to attempt to stop smoking, and more likely than exclusive smokers to try to quit, there were no significant differences in quitting success.[42]

In much of this research, the authors are cautiously optimistic about the role ENDS products play in smoking cessation while noting that additional studies are needed to provide more clarity, especially with regard to effect size and duration of abstinence. To offer a larger scale estimate of the health gains associated with e-cigarettes, modelers ran 360 scenarios in which individuals quit smoking either with or without e-cigarettes. In 357 of those scenarios (99 percent), quitting by vaping saved more "life years" than quitting without. This amounted to a net benefit ranging from 143,000 to 65-million life years, with the average individual gaining between 1.2 and 2 years by using e-cigarettes to aid in their cessation.[43]

Furthermore, it is noteworthy that reducing the harms associated with tobacco use does not necessarily require absolute cessation. While the ideal public health outcome would be for all people to completely quit smoking, individuals who simply reduce their daily tobacco intake may also experience benefits. One study of individuals who both smoke and vape found that when compared to exclusive smokers, these dual users have lower levels of a range of telltale toxins, including cotinine, exhaled carbon monoxide and urinary 3-HMPA.[44] Another study—this one a 12-month randomized controlled trial—found that systolic blood pressure fell significantly from baseline levels among smokers who had started with high blood pressure and had successfully quit or reduced cigarette use by at least 50 percent during the course of the study.[45]

Thus, many smokers are able to glean health benefits from using ENDS products, even if they do not quit entirely. While less attention has been paid to e-cigarette's role in reduction, one survey conducted in the United States and Canada found that 83.3 percent of 1099 "concurrent users"—those who used both electronic and combustible cigarettes—reported that vaping helped them reduce their smoking.[46] Another study showed that individuals who struggled with the highest degrees of nicotine addiction benefited the most from e-cigarette use. While vaping had little to no relationship with smoking frequency for those with mild to moderate dependence, it was associated with smoking fewer cigarettes among those for whom nicotine dependence was severe.[47]

Moreover, data increasingly suggest that for many e-cigarette users, non-tobacco flavors contribute to enjoyment of the vaping experience.[48] Indeed, according to the Tobacco and Health Study, 90.3 percent of 961 adults aged 18 to 24 and 66.4 percent of 1711 adults aged 25 and older reported that flavors were one of the reasons that they opted to vape.[49]

In turn, this enjoyment could actually help smokers initiate and maintain the transition from combustible cigarettes to ENDS products. A 2020 study found that 86.6 percent of participants who were vaping to reduce smoking chose candy flavors and 86.2 percent vaped fruit flavors.[50] Perhaps even more compelling, sweet flavors are gaining popularity among individuals who are actively transitioning away

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42. Sarah E. Jackson et al., "Associations between dual use of e-cigarettes and smoking cessation: A prospective study of smokers in England," *Addictive Behaviors*, 103 (April 2020). https://www.sciencedirect.com/science/article/pii/S0306460319309785.

43. David Mendez and Kenneth E. Warner, "A Magic Bullet? The Potential Impact of E-Cigarettes on the Toll of Cigarette Smoking," *Nicotine & Tobacco Research* (Aug. 21, 2020). https://pubmed.ncbi.nlm.nih.gov/32823272.

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46. Shannon Gravely et al., "The Association of E-cigarette Flavors With Satisfaction, Enjoyment, and Trying to Quit or Stay Abstinent From Smoking Among Regular Adult Vapers From Canada and the United States: Findings From the 2018 ITC Four Country Smoking and Vaping Survey," *Nicotine & Tobacco Research* 22:10 (October 2020), pp. 1831-1841. https://academic.oup.com/ntr/article/22/10/1831/5843872?login=true.

47. Arielle S. Selya et al., "The Role of Nicotine Dependence in E-Cigarettes' Potential for Smoking Reduction," *Nicotine & Tobacco Research* 20:10 (Sept. 4, 2018), pp. 1272-1277. https://pubmed.ncbi.nlm.nih.gov/29065204.

48. Gravely et al., 2020, pp. 1831-1841. https://academic.oup.com/ntr/article/22/10/1831/5843872?login=true.

49. Samir S. Soneji et al., "Use of Flavored E-Cigarettes Among Adolescents, Young Adults, and Older Adults: Findings From the Population Assessment for Tobacco and Health Study," *Public Health Report*, 143: 3 (March 12, 2019), pp. 282-292. https://journals.sagepub.com/doi/full/10.1177/0033354919830967.

50. Gravely et al., 2020, pp. 1831-1841. https://academic.oup.com/ntr/article/22/10/1831/5843872?login=true.

from combustible and toward electronic cigarettes. A multi-wave online survey of 20,836 frequent users of e-cigarettes in the U.S. showed that prior to 2011, only 17.8 percent of first e-cigarette purchases were flavored. By 2015 and 2016, that number had nearly doubled. During this same period, tobacco flavors fell out of favor, declining from 40 percent to 24 percent of first e-cigarette purchases.[51]

Thus, a ban on flavors potentially hinders harm reduction benefits by reducing the appeal of e-cigarettes for adult smokers. In a qualitative study of 25 U.S.-based smokers aged 18 to 34 who reported using ENDS products to cut back on smoking, most participants indicated that e-cigarette flavors affected their ability and desire to cut back on combustible cigarettes. The majority of participants reported enjoying flavors and many explained that the assortment kept them interested and less likely to revert to smoking. While some said they liked that tobacco and menthol flavors made vaping more reminiscent of smoking, others found the opposite. In particular, many participants fretted about losing access to fruit and candy flavors, noting that the tobacco flavor triggered urges to smoke combustible cigarettes.[52]

Other Impacts of a Flavor Ban

Counterfeit products and black markets account for an estimated 5 percent of goods sold worldwide[53] and between 2.5 and 10 percent of global trade.[54] Tobacco is already a vulnerable market to counterfeit and contraband products—according to a multi-agency report, cigarettes are among the most smuggled 'legal' products in the world.[55] In Canada, contraband products are estimated to account for 20 to 30 percent of the cigarette market.[56] In January 2021, the FDA and Customs and Border Patrol (CBP) seized 33,861 units of contraband and counterfeit e-cigarettes with a retail value of nearly $80,000; in 2020, the organizations seized 93,590 units of e-cigarettes that did not meet U.S. federal regulations.[57] Further, internet and app-based retailers, popular sales platforms for e-cigarettes, are exceedingly challenging to monitor and regulate, especially for local and state authorities.[58]

Beyond the economic threats posed by such illicit or unregulated markets, experts rightly worry that they can endanger the public, as they tend to result in "more readily concealed and more dangerous forms of what is prohibited."[59] Indeed, in a 2016 report the U.S. Chamber of Commerce estimated that deaths resulting from counterfeit products in G20 countries cost more than $18 billion. Including the cost of counterfeit product-related illness or injury adds another $125 million.[60]

When it comes to witnessing the potential dangers of unauthorized e-cigarettes, one of the most highly publicized examples is the outbreak of e-cigarette or vaping product use-associated lung injury (EVALI) associated with vaping. Between August 2019 and February 2020, EVALI led to the death or hospitalization of more than 2,800 people.[61] While public health experts are still investigating the precise cause, a small but growing body of research points to certain cannabis-based and especially counterfeit products.[62] In fact, counterfeit and "street" cartridges for cannabis-based e-cigarettes have been found to contain a number of potential toxicants that are not present in either regulated or medical-grade versions.[63]

But less extreme examples exist as well, suggesting that the issue is not limited to this one outbreak, but to a wider range of risks. For example, in a study of authentic versus counterfeit e-cigarettes across four countries—the United States, England, China and Nigeria—demonstrated that 81.3 percent of counterfeit products labeled nicotine-free contained nic-

51. 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 (June 28, 2018). https://harmreductionjournal.biomedcentral.com/articles/10.1186/s12954-018-0238-6.

52. Julia Cen Chen et al., "Perceptions about e-cigarette flavors: a qualitative investigation of young adult cigarette smokers who use e-cigarettes," *Addiction Research & Theory* (Jan. 22, 2019), pp. 420-428. https://www.tandfonline.com/doi/abs/10.1080/16066359.2018.1540693?journalCode=iart20.

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54. U.S. Chamber of Commerce, *Measuring the Magnitude of Global Counterfeiting: Creation of a Contemporary Measure of Physical Counterfeiting*, 2016. https://www.uschamber.com/sites/default/files/documents/files/measuringthemagnitudeofglobalcounterfeiting.pdf.

55. U.S. Department of State, "The Global Illicit Trade in Tobacco: A Threat to National Security," December 2015. https://2009-2017.state.gov/documents/organization/250513.pdf.

56. Peter Reuter, "Can tobacco control endgame analysis learn anything from the US experience with illegal drugs?" *Tobacco Control* 22 (2013), pp. i49-i51. https://tobaccocontrol.bmj.com/content/22/suppl_1/i49.

57. Allison Hunt, "CBP, FDA Seize Counterfeit, Unauthorized E-Cigarettes," U.S. Food and Drug Administration, Jan. 13, 2021. https://www.fda.gov/news-events/press-announcements/cbp-fda-seize-counterfeit-unauthorized-e-cigarettes#:~:text=In%20fiscal%20year%202020%2C%20CBP,not%20meet%20U.S.%20federal%20regulations.&text=.

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59. Reuter, pp. i50. https://tobaccocontrol.bmj.com/content/22/suppl_1/i49.

60. Global Intellectual Property Center, *Measuring the Magnitude of Global Counterfeiting: Creation of a Contemporary Global Measure of Physical Counterfeiting*, U.S. Chamber of Commerce, 2016. https://www.uschamber.com/sites/default/files/documents/files/measuringthemagnitudeofglobalcounterfeiting.pdf

61. Thivanka Muthumalage et al., "Chemical Constituents Involved in E-Cigarette, or Vaping Product Use-Associated Lung Injury (EVALI)," *Toxics*, 8:2 (April 3, 2020). https://www.mdpi.com/2305-6304/8/2/25

62. Lozier et al., 2019, pp. 1142-1148. https://www.cdc.gov/mmwr/volumes/68/wr/mm6849e1.htm; Blount et al., 2020, pp. 697-705. https://www.nejm.org/doi/full/10.1056/NEJMoa1916433.

63. Navon et al., 2019, pp. 1034-1039. https://www.cdc.gov/mmwr/volumes/68/wr/mm6845e1.htm.

otine.[64] Counterfeit ENDS products are also more likely to contain exploding batteries, which have resulted in serious injury from broken teeth to facial burns and even pose a risk to any potential handler, such as airline employees.[65]

LOST REVENUE AND THE POTENTIAL PUBLIC HEALTH TRADEOFF

In addition to the direct effect flavor bans could have on the health of e-cigarette consumers (or those on-the-brink of conversion), they also have the potential to affect community health and well-being by reducing key funds. Tobacco taxes are sometimes used to fund programs aimed at smoking prevention and cessation—at the federal level, for example, one program that receives tobacco tax revenue is CHIP, the Children's Health Insurance Program—but the majority winds up elsewhere.[66]

There is of course considerable variation across states, but in fiscal year 2020, states spent only $739.7 million on tobacco prevention—that is 3 percent of the $27.2 billion they received from tobacco taxes and industry settlements.[67] Although this proportion seems low, many states allocate additional funds to broader health programs that benefit the entire state or vulnerable populations. In Colorado, for example, revenue from tobacco taxes is divvied up between the general fund, tobacco education and prevention, as well as specific funds aimed at expanding access to healthcare and providing financial assistance and medical benefits to low-income older adults.[68] In Georgia—where tobacco taxes have been among the lowest in the nation—calls to increase that revenue stream claimed that the funds could be used not only for smoking cessation and prevention efforts, but also as an investment in "health services that benefit everyone."[69] In fiscal year 2020, state estimates for vaping taxes ranged from $1 million to $10 million in revenues.[70] And as of Dec. 15, 2020, 27 states plus Washington, D.C., Puerto Rico and the U.S. Virgin Islands had enacted some sort of tax on e-cigarettes.[71]

States that are considering, or have already enacted flavor bans, are already grappling with what the loss of this revenue could mean for their coffers. When Colorado considered a ban on all flavored nicotine products in early 2020, a fiscal review estimated that the proposed law could cost the state at least $33 million per year.[72] In fiscal year 2020, the first year after enacting its flavor ban, Massachusetts saw a $50 million decline in revenue from tobacco taxes. Estimates for 2021 suggest that the state could take an even bigger hit—as much as $120 million.[73]

Moreover, if we use Massachusetts as a model for what is to come, uneven prohibition measures could cost states revenue without reducing actual tobacco and nicotine use. As discussed above, Massachusetts vapers and smokers have already been crossing state lines to access preferred products. As such, neighboring states are reaping the tax revenues.[74]

Whereas cigarette tax revenue losses associated with expanded cigarette regulations are generally offset by subsequent reductions in chronic disease, it is unlikely that e-cigarette flavor bans will have the same balance.[75] And, given the above predictions regarding possible behavior changes—whether individuals revert to smoking or purchase products outside of the ban areas—states that enact a flavor ban risk losing some of those funds while potentially driving new public health challenges.

CONCLUSION

The primary motivation for tobacco control has traditionally been the mitigation of disease and death, especially that associated with smoking combustible cigarettes. Held to this standard, it is unclear that expanding regulations on ENDS products to ban flavors could meet intentions. While not completely risk-free, e-cigarettes do not contain the toxins

64. Esther E. Omaiye et al. "Counterfeit Electronic Cigarette Products with Mislabeled Nicotine Concentrations," *Tobacco Regulatory Science* 3:3 (July 2017), pp. 374-357. https://pubmed.ncbi.nlm.nih.gov/29744375.

65. Saurabh Saxena et al. "Exploding E-Cigarettes: A Battery Safety Issue," *IEEE Access* 6 (March 30, 2018), pp. 21442-21466. https://ieeexplore.ieee.org/document/8328814.

66. "Cigarette & Tobacco Taxes," American Lung Association, Dec. 10, 2020. https://www.lung.org/policy-advocacy/tobacco/tobacco-taxes.

67. State Tobacco Activities Tracking and Evaluation (STATE) System, "STATE System Excise Tax Fact Sheet," Centers for Disease Control and Prevention, Dec. 14, 2020. https://www.cdc.gov/statesystem/factsheets/excisetax/ExciseTax.html.

68. "Cigarette Tax," Colorado Legislative Council Staff, Feb. 8, 2021. https://leg.colorado.gov/agencies/legislative-council-staff/cigarette-tax#:~:text=Twenty%2Dseven%20percent%20of%20this,a%20given%20city%20or%20county.&text=A%20majority%20of%20Amendment%2035,required%20by%20the%20Colorado%20Constitution.

69. Laura Harker, "Increase the State Tobacco Tax for a Healthier Georgia," Georgia Budget & Policy Institute, Dec. 4, 2018. https://gbpi.org/tobacco-tax-increase/#:~:text=The%20cigarette%20tax%20would%20bring,substance%20use%20services%20and%20Medicaid.

70. "E-Cigarette & Vaping Product Taxes," National Conference of State Legislatures, April 6, 2020. https://www.ncsl.org/research/fiscal-policy/electronic-cigarette-taxation.aspx.

71. Public Health Law Center, "E-Cigarette Tax: States with Laws Taxing E-Cigarettes," Mitchell Hamline School of Law, Dec. 15, 2020. https://www.publichealthlawcenter.org/sites/default/files/States-with-Laws-Taxing-ECigarettes-Dec2020.pdf.

72. Daley, 2020. https://www.cpr.org/2020/03/04/proposed-ban-on-flavored-nicotine-and-tobacco-has-a-money-problem.

73. Boesen, 2021. https://taxfoundation.org/massachusetts-flavored-tobacco-ban/#:~:text=Massachusetts%20collected%20%24557%20million%20in,revenue%20of%20roughly%20%2450%20million.

74. Zeninjor Enwemeka, "'Thank You, Gov. Baker': N.H. Vape Shops See Rush After Mass. Ban," WBUR, Oct. 9, 2019. https://www.wbur.org/bostonomix/2019/10/09/massachusetts-vaping-ban-new-hampshire-sales-boost; Naomi Martin, "Mass. banned vape sales more than two months ago. And now business in N.H. and Maine is booming," *The Boston Globe*, Dec. 4, 2019. https://www.bostonglobe.com/metro/2019/12/04/vape-sales-boom-maine-amid-mass-ban/PQe8dPdlnuPYsEIU1SprRK/story.html; Boesen, 2021. https://taxfoundation.org/massachusetts-flavored-tobacco-ban/#:~:text=Massachusetts%20collected%20%24557%20million%20in,revenue%20of%20roughly%20%2450%20million.

75. Harker, 2018. https://gbpi.org/tobacco-tax-increase/#:~:text=The%20cigarette%20tax%20would%20bring,substance%20use%20services%20and%20Medicaid.

that make combustible cigarettes so dangerous. They have therefore been deemed safer alternatives, especially for smokers looking to quit. Nonetheless, advocates for flavor bans emphasize that they would prevent youth uptake of vaping, thereby squashing the likelihood that a new generation will grow up with a nicotine addiction.

Of particular relevance, however, restrictions have a history of affecting diverse groups differently. While experienced consumers are most likely to weather tax increases, they are also more likely to "find a way" to access favorite products. In the case of ENDS flavor bans, this could mean experienced vapers are the ones who will shop online, cross borders or open themselves up to illicit markets. Conversely, those attempting to transition may be more likely to give up and revert to what is most familiar. This is where individuals hoping to quit smoking combustible cigarettes in exchange for vaping ENDS products are most vulnerable: If the product that drew them to vaping is no longer available, they may be less likely to quit.

The federal government has already sought to regulate youth access to ENDS products through age-specific legislation, the latest of which has not yet been adequately evaluated. Additional policies that restrict flavors, especially if they are carried out at a state or local level, come with potential health consequences of their own. Furthermore, the potential loss of tax revenue that comes from a product that has thus far been deemed reasonably safe could make it more difficult for states to invest broadly in the health of their populations. Thus, even if the proposed restrictions have effects on youth vaping above and beyond those of age minimums, the increased potential among adults to engage with illicit markets or give up on smoking cessation efforts, could result in a net public health loss.

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