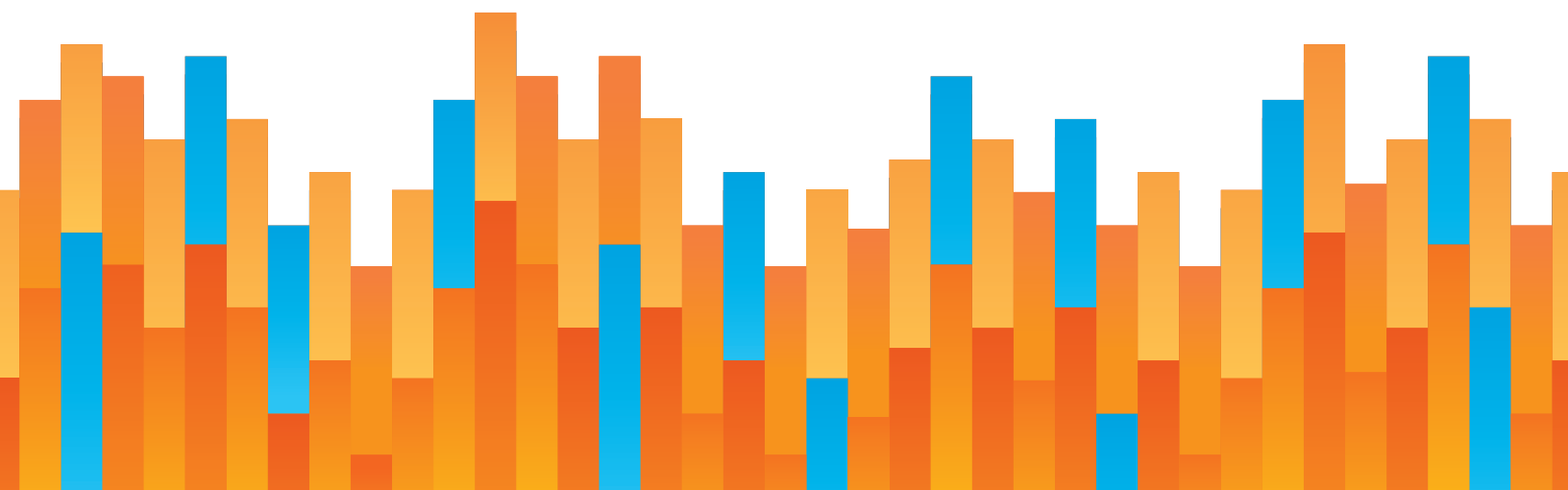




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A QUESTION OF TASTE: THE PUBLIC HEALTH CASE FOR E-CIGARETTE FLAVORS

by Guy Bentley
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EXECUTIVE SUMMARY

Flavored tobacco products have long been the subject of controversy, especially with regards to their potential appeal to youth. In 2009, the federal government banned the manufacture and sale of all combustible cigarettes flavored to taste like clove, candy or fruit, but made an exception for menthol. The reason given for banning these products is that certain flavors could be especially attractive to children, luring them into smoking and serving as a gateway to lifelong cigarette addiction.

The debate over e-cigarette flavors is fundamentally different from the one over flavored cigarettes. Unlike combustible cigarettes, e-cigarettes are a harm reduction product that offers smokers a significantly less dangerous alternative to smoking cigarettes. To do so, they deliver nicotine and/or flavorings that consumers want in a vapor that contains far fewer toxicants than cigarette smoke, the inhalation of which leads to the deaths of more than 480,000 Americans every year.

“

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When FDA Commissioner Scott Gottlieb announced an advanced notice of proposed rulemaking (ANRPM) on the regulation of flavored tobacco products in March 2018, he recognized the role flavors can play in tobacco harm reduction:

I've talked to ex-smokers, who've told me that they quit cigarettes altogether and that they now vape. And they've also told me it was the flavors that helped them make that transition off combustible cigarettes. Now I know anecdotes aren't the same as data. And the ANPRM specifically seeks data on this issue. But these personal stories are important to me as we shape our overall approach to smoking cessation.

Gottlieb has since emphasized that while e-cigarettes can play a role in reducing tobacco-related harms, it must not come at the expense of addicting a new generation of teens to nicotine. Gottlieb echoes the main objection to the widespread availability of e-cigarettes and their promotion as a tool for smoking cessation. While they may present a benefit for adult smokers, critics argue, they could prove a threat to adolescents. So-called “kid-appealing” flavors are regularly singled out as targeting children and being of little interest to adult smokers trying to switch to vaping.

In September 2018, FDA Commissioner Scott Gottlieb announced that e-cigarette use among teenagers had reached “epidemic” levels. To combat this alleged epidemic, Gottlieb asked the nation’s five largest e-cigarette manufacturers to submit plans to tackle youth use. If these plans do not meet FDA’s approval, all non-tobacco flavors could be withdrawn from the market, and the deadline for e-cigarette product applications could be brought forward from the current 2022 deadline. If implemented, these policies could provide a devastating and possibly irreparable blow to the independent e-cigarette industry.

While flavor plays a role in the decision of some youth to try vaping, the evidence shows that it is one of many factors and is often not the leading reason for youth vaping. Curiosity, peer influence, and rebellion are also major influences as they are with youth use of many adult products. There is no reason to believe that banning e-cigarette flavors would, in fact, reduce youth vaping. Removing these flavors would not necessarily alter their decision to experiment with e-cigarettes to begin with. It is a leap in logic to suggest that without a variety of flavors kids would not experiment with e-cigarettes as they do with other adult products such as alcohol.

In this way, the role e-cigarette flavors play in youth vaping initiation is grossly exaggerated. As well, while all youth use of e-cigarettes is undesirable, rates of use are not

significantly higher than other adult products that teens experiment with. In fact, youth e-cigarette use is lower than for other illicit products.

Nonetheless, non-tobacco flavors are consistently labeled “kid-appealing.” While it is true that the majority of kids who vape use non-tobacco flavors, that is not the end of the story. Non-tobacco flavors such as fruit, dessert, and pastry are in fact the most popular choices among adult vapers also. According to the largest surveys ever conducted, most adults switching from cigarettes to vaping opt to switch with a non-tobacco flavor. Increasingly, literature both from testimonials and longitudinal studies shows that flavor varieties assist smoking cessation among adult smokers who switch to vaping. There is nothing in the data to suggest that non-tobacco flavors are inherently and solely “kid-appealing,” that adults do not like flavors, or that e-cigarette companies use these flavors to target minors.

While debates over the possible long-term impact of e-cigarette use remain a subject of intense discussion, there is an overwhelming consensus that these products are significantly less harmful than cigarettes and can play an essential role in helping adult smokers quit. A substantial emerging literature demonstrates that the majority of adult vapers use flavored products when transitioning away from cigarettes and maintaining cigarette abstinence. As such, e-cigarettes are a harm reduction product in that they pose vastly less danger to their users than traditional cigarettes, and smokers who switch to these products will dramatically lower their risk of smoking-related disease.



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As it stands, there is no justification by way of scientific evidence or consumer welfare analysis for a tobacco product standard prohibiting or severely limiting the number of e-cigarette flavors. Developing such a standard would be counterproductive, degrading the appeal and user experience of products which, when used exclusively in place of combustible cigarettes, dramatically reduce the risks of tobacco-related disease. The FDA itself has stated that e-cigarettes are a vital part of the policy mix to reduce deaths from

smoking, and Scott Gottlieb has said that if every smoker in America switched to e-cigarettes, it would be a net benefit to public health.

The key objective for FDA should be to maximize the public health potential of e-cigarettes by ensuring widespread availability of e-cigarette products in the forms that actually appeal to adult smokers, which is for the most part in non-tobacco flavors. At the same time, FDA must use its authority to limit sales of these products to youth as much as possible.

To tackle youth use, FDA should use its enforcement power to prevent and punish illegal sales of these products to minors. But banning or severely restricting the most popular category of a tobacco harm reduction product in order to tackle underage use is misguided and presents a net harm to public health by removing a popular option for adult smoking cessation.

The FDA does not have to make a choice between helping adults quit smoking and preventing youth from vaping. A sensible regulatory policy can achieve both these objectives at the same time. If FDA gets the correct balance between enforcement and ensuring a thriving market for tobacco harm reduction products, the results could be millions of lives saved.

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PART 1

INTRODUCTION

Invented in 2003 by the Chinese pharmacist Hon Lik, e-cigarettes have developed into a multi-billion dollar industry. Known as vaping, e-cigarette use has become the most popular method of smoking cessation in both the U.S. and U.K. A host of public health advocates and organizations have cheered this development as a successful and potentially revolutionary method of tobacco harm reduction. For those smokers who cannot or do not want to quit smoking using traditional nicotine replacement therapies, harm reduction products such as e-cigarettes offer a substantially safer way to consume nicotine without the deadly smoke that kills half of lifelong smokers. As the FDA has made clear and has been known in the public health community for decades, it is the smoke from combustion—not nicotine—which kills smokers.

According to Public Health England¹ and the Royal College of Physicians,² e-cigarettes are unlikely to exceed 5% of the risks of traditional cigarettes. But as with most new products, there are risks as well as benefits. The great benefit of e-cigarettes is transitioning adult

¹ Public Health England. “E-cigarettes: an evidence update.” August 19, 2015. <https://www.gov.uk/government/news/e-cigarettes-around-95-less-harmful-than-tobacco-estimates-landmark-review>

² Amos, Amanda et al. “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>

smokers to a safer form of nicotine consumption, potentially saving millions of lives. The danger is that a new generation who would not otherwise have used any tobacco or nicotine product will start using e-cigarettes at a young age and develop an addiction to nicotine. This is a challenge FDA is trying to grapple with. Public health bodies are concerned about the prevalence of youth vaping and new data suggesting a substantial rise in teen vaping between 2017 and 2018.

One culprit that has been singled out as a major cause of youth vaping is the varieties of e-cigarette flavors. Anti-tobacco groups and some politicians accuse e-cigarette companies of marketing these flavors to kids, asserting that they do not and are not intended to appeal to adult smokers. The FDA and anti-tobacco campaigners are concerned that e-cigarettes with sweet or fruit flavors may be appealing to children, creating a new generation of nicotine-addicted teenagers, and that youth use of e-cigarettes could act as a gateway to smoking. Skeptics of e-cigarette flavors also doubt their relevance or efficacy in making e-cigarettes an effective harm reduction product that smokers will find appealing and achieve long-term smoking cessation.



Flavored tobacco products have long been the subject of controversy, especially with regards to their potential appeal to youth.



Flavored tobacco products have long been the subject of controversy, especially with regards to their potential appeal to youth. In 2009, the federal government banned the manufacture and sale of all combustible cigarettes flavored to taste like clove, candy or fruit, but made an exception for menthol.³ The reason given for banning these products is that certain flavors could be especially attractive to children, luring them into smoking and serving as a gateway to lifelong cigarette addiction.

³ Layton, Lyndsey. "Federal Ban on Flavored Cigarettes Takes Effect." *Washington Post*. September 22, 2009. <http://www.washingtonpost.com/wp-dyn/content/article/2009/09/22/AR2009092201740.html?noredirect=on>

In March 2018, the Food and Drug Administration (FDA) issued an advanced notice of proposed rulemaking (ANPRM) regarding the regulation of flavored tobacco products.⁴ FDA regulations could include a ban on menthol cigarettes, flavored smokeless tobacco and some or even all non-tobacco e-cigarette flavors. Although they contain no leaf tobacco, e-cigarettes are categorized as tobacco products and are regulated under the authority of the FDA.

In September 2018, FDA Commissioner Scott Gottlieb announced that e-cigarette use among teenagers had reached “epidemic” levels.⁵ To combat this alleged epidemic, Gottlieb asked the nation’s five largest e-cigarette manufacturers to submit plans to tackle youth use. If these plans do not meet FDA’s approval, all non-tobacco flavors could be withdrawn from the market, and the deadline for e-cigarette product applications could be brought forward from the current 2022 deadline. Such intentions pit prevention of youth vaping against the health benefits of helping adults—and possibly youth—quit smoking.

⁴ Food and Drug Administration. “Regulation of Flavors in Tobacco Products: A Proposed Rule by the Food and Drug Administration.” March 21, 2018.
<https://www.federalregister.gov/documents/2018/03/21/2018-05655/regulation-of-flavors-in-tobacco-products>

⁵ Gottlieb, Scott. “Statement from FDA Commissioner Scott Gottlieb, M.D., on new steps to address epidemic of youth e-cigarette use.” September 12, 2018.
<https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm620185.htm>

PART 2

THE APPEAL OF E-CIGARETTE FLAVORS TO YOUTH

The chief concern driving fears around e-cigarette flavors is their appeal or potential appeal to youth. Tobacco Control advocates warn that flavored e-cigarettes entice young people to start vaping, which could, in turn, lead to nicotine addiction, which it is argued has the potential to rewire adolescent brains to be more vulnerable to other risky behaviors such as drug or alcohol abuse.

The assumption is that children who would not usually experiment with vaping do so precisely because they come in certain flavors. If these non-tobacco flavors were prohibited or severely restricted, the appeal of these products to young people would be dramatically reduced, according to this line of thinking.

Before tackling these concerns, it is important to keep four points in mind. First, adolescents experiment with many illicit and risky behaviors. According to the Monitoring the Future Survey of 2017, 19.7% of 10th graders used alcohol in the past month, and 15.7% used cannabis, despite both these products being illegal for sale to minors.⁶

⁶ Johnston, LD, et al. "Monitoring the Future national survey results on drug use, 1975-2017." Institute for Social Research, The University of Michigan. January, 2018.
<http://monitoringthefuture.org/pubs/monographs/mtf-overview2017.pdf>

According to the same survey, 8.2% of 10th graders said they vaped in the past 30 days. Unfortunately, teenagers engage in a range of adult behaviors in which they are prohibited from participating. As long as e-cigarettes are legally available to adults, it is extremely unlikely that youth use of these products will be zero whether flavors exist or not. Recreational cannabis remains illegal in most states, but youth use is widespread and significantly outstripped vaping in 2017.



As long as e-cigarettes are legally available to adults, it is extremely unlikely that youth use of these products will be zero whether flavors exist or not.



Second, when examining whether flavored e-cigarettes appeal to youth, we have to ask: which youths? It should not come as a surprise that those youths who have already used other tobacco products like cigarettes, little cigars, or smokeless tobacco may have a propensity to using e-cigarettes. They have already shown a willingness to experiment with tobacco products and in some cases may be using e-cigarettes to replace other, more dangerous forms of tobacco use such as smoking. When examining the role, or lack thereof, that flavors play in enticing youth to use e-cigarettes, the critical group to consider is those who have never used any other tobacco product but for one reason or another are attracted to e-cigarettes that are not tobacco-flavored. In short, are flavored e-cigarettes drawing youth who would otherwise not be using tobacco products, and are flavors the principal reason for this use?

Third, when examining the available evidence, it is essential to look at how youth act rather than how they say they will act. A non-smoking teenager who says she's interested in trying a flavored e-cigarette but fails to do so does not make a case for restricting these products, or that these products are inherently appealing to children.

Fourth, if non-smoking youths do experiment with flavored e-cigarettes, does this experimentation lead to frequent use or even addiction?

The claim that e-cigarette flavors are especially appealing to children, particularly those who have never used any tobacco product, is made extensively but lacks substantive empirical support. While flavors may be a factor in some teenagers' decisions to experiment

with e-cigarettes, there is no convincing evidence that flavors in and of themselves are recruiting large numbers of non-smoking teens to vape or inducing widespread nicotine addiction. Many studies purporting to show a strong interest among youth in flavored e-cigarettes, in fact, show no such thing or suffer from limitations so severe as to render their conclusions and recommendations irrelevant.

2.1

THE SURGEON GENERAL RAISES THE ALARM

Former Surgeon General Vivek Murthy's 2016 report on e-cigarette use among youth and young adults is widely cited as a source for concern about e-cigarette flavors. The report highlights that youth were more likely than adults to opt for flavored combustible cigarettes before Congress legislated to ban such flavors with an exception being made for menthol.

Murthy argued a similar concern surrounds e-cigarette flavors and that this concern is "supported by studies indicating that youth and young adults who have ever used e-cigarettes begin their use with sweet flavors rather than tobacco flavors." What should be noted is the broadness of such a statement. Murthy says youth who have "ever used" an e-cigarette. This would include all minors who have taken one puff of an e-cigarette and never used again as well as current users. It also fails to attribute causation. Murthy does not say flavors are the reason minors used an e-cigarette, merely that those who did mostly used flavors. Nowhere does the report make a causal claim, only that the issue is of concern given the previous history of tobacco products. The report also fails to clarify how many of those who had ever used an e-cigarette also used cigarettes or other tobacco products before they initiated e-cigarette use. "The concern, among youth, is that the availability of e-cigarettes with sweet flavors will facilitate nicotine addiction and simulated smoking behavior—which will lead to the use of conventional tobacco products," says Murthy.

Murthy cites three studies that purport to justify his concern. It should be noted that none of the studies mentioned claim e-cigarette use among minors will lead to the use of conventional tobacco products. Instead, the studies analyze reasons for youth use of e-cigarettes and the prevalence of flavors. The first study cited in the report from Kong et al. examines the reasons for e-cigarette experimentation and discontinuation among adolescents and young adults.⁷ The study used a combination of focus groups and school-wide surveys.

⁷ Kong, Grace, et al. "Reasons for Electronic Cigarette Experimentation and Discontinuation Among Adolescents and Young Adults." *Nicotine & Tobacco Research*. 2014;17(7):847-54. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4674436/>

According to the survey data, the top three reasons for e-cigarette experimentation among lifetime e-cigarette users, regardless of cigarette smoking status and school level, were curiosity (54.4%), the availability of appealing flavors (43.8%), and friends' influence (31.6%). Specifically, high-school students were more likely to experiment with e-cigarettes because of appealing flavors than college students, 47% vs. 32.8%. However, the principal reason for use among high school students was curiosity at more than 50%. Furthermore, when "ever" cigarette smokers were asked about their reasons for e-cigarette experimentation, flavors ranked sixth place, and for current cigarette smokers, flavors ranked seventh place. By an overwhelming margin, the main reason for e-cigarette experimentation among ever smokers and current smokers was to quit smoking. This is an important point, as ever smokers and current smokers are significantly more likely to experiment with e-cigarettes than never smokers as they have shown a propensity to experimenting with tobacco products. The availability of e-cigarettes, in this case, is not facilitating nicotine addiction but is instead acting as an alternative to cigarettes.



By an overwhelming margin, the main reason for e-cigarette experimentation among ever smokers, and current smokers was to quit smoking.



Among focus group participants, almost 60% of high schoolers who reported "current" use of an e-cigarette were smokers, with fewer than 5% of non-smokers reporting current use of an e-cigarette. No middle school students in the focus group reported using an e-cigarette. The study's authors also make clear the limitation of this research, stating: "The cross-sectional nature of the survey and the focus groups precludes us from making causal statements." But even with severe limitations, the study makes clear that harm reduction and curiosity were the leading causes of e-cigarette use, not flavors.

The second study cited was from Krishnan-Sarin et al. examining vaping among middle and high school students in Connecticut. While the majority of never smokers who vaped used

sweet flavors—68.6%—just 2.1% of middle school students and 13.2% of never smoking high school students reported they had even tried an e-cigarette.⁸

The figures for never smoking students who vaped in the past 30 days were even lower, at just 0.9% for middle school students and 4.6% high school students. Current e-cigarette use for all high school students was 12% and 1.5% for middle school students.

TABLE 1: CURRENT VAPING RATES, MIDDLE AND HIGH SCHOOLERS IN CONNECTICUT (PAST 30-DAY USE OF E-CIGARETTES)

	Never-smokers	Ever-smokers	Current smokers
Middle school	0.9%	10.5%	30%
High school	4.6%	23.5%	64.1%

As with most studies, interest in e-cigarettes from never smokers was extremely limited. But for the purpose of examining the appeal of e-cigarette flavors to youth, it is important to note that the authors “did not have a specific hypothesis about flavors.” Rather, the study’s authors sought to explore if the use of specific flavors differed among smokers.

“A central concern is that e-cigarette use among this potentially vulnerable population, who had tried cigarettes but decided not to continue, may lead to re-initiation of cigarette use and/or progression to regular use of various tobacco products,” said the study’s authors. “Alternatively, it also is possible that students who tried cigarettes in the past used e-cigarettes to quit smoking; further research to explore this issue is imperatively needed.”

The authors add that “these data were based on adolescent self-reports and were cross-sectional in nature and therefore cannot be used to draw temporal conclusions.” The study in no way provides evidence or even a hypothesis that e-cigarette flavors are especially appealing to youth. While the study raises concerns about a “gateway” to future tobacco use, it provides no empirical evidence to justify these concerns.

⁸ Krishnan-Sarin, Suchitra et al. “E-cigarette Use Among High School and Middle School Adolescents in Connecticut.” *Nicotine & Tobacco Research*. vol. 17,7 (2014): 810-8. <https://www.ncbi.nlm.nih.gov/pubmed/25385873>

The third study cited in Murthy's report is based on a 2016 analysis of the 2013-14 Population Assessment of Tobacco and Health (PATH) survey.⁹ The study is a cross-sectional analysis of data on flavored tobacco use among 13,651 youth (ages 12-17) in Wave 1. Of these, 3.1% had used an e-cigarette within the last 30 days. When asked why they used e-cigarettes, 81% of teens who vaped in the past month answered "yes" to the statement: "because they come in flavors I like." While these responses appear to lend credence to the argument that e-cigarette flavors are especially appealing to youth, they're actually of minimal value.

It would be highly eccentric for those already using a product to say they did so because it came in flavors they didn't like or to use a product whose flavor they did not enjoy. In fact, it would be more worrying if they said they did not enjoy these flavors as it would show they were using these products in spite of a dislike of the flavor.

It's also not the only reason teens gave for vaping. According to the same survey, 79% of respondents said they use e-cigarettes because "they might be less harmful to me than cigarettes," while 78% said they did so because "they might be less harmful to people around me than cigarettes." Even among those who cited flavors as important in their decision to vape, a re-analysis of the data showed that 92% said harm reduction was a motivating factor.



According to the same survey, 79% of respondents said they use e-cigarettes because "they might be less harmful to me than cigarettes," while 78% said they did so because "they might be less harmful to people around me than cigarettes."



The studies cited in the surgeon general's report fall well short of justifying the concerns raised about the threat e-cigarette flavors may present to youth. The studies in no way show that e-cigarette flavors are especially appealing to youth as opposed to adults, or that

⁹ Ambrose, Bridget K., et al. "Flavored Tobacco Product Use Among US Youth Aged 12-17 Years, 2013-2014" *Journal of the American Medical Association*. November 3, 2015. <https://jamanetwork.com/journals/jama/fullarticle/2464690>

non-smoking youth are more likely to be attracted to e-cigarettes due to their flavors as opposed to peer influences or curiosity.

The surgeon general was correct to point out that the majority of ever e-cigarette users among youth used a sweet flavor, but what wasn't highlighted was the fact that the vast majority of them were current or former smokers. There is also no suggestion in any of the studies cited in Murthy's report that flavored e-cigarettes are a causal mechanism for transitioning to smoking.

According to the data cited, e-cigarettes are of little interest to those who have never smoked and flavors are one of many reasons why some youth decide to vape. The fear-based claims of anti-vaping advocates based on the surgeon general's report are wildly overblown in relation to the actual evidence presented.

2.2

NEW EVIDENCE EMERGES

A more recent and widely cited piece of evidence offered in support of the view that e-cigarette flavors are appealing to youth is a study based on a national phone survey which found teens were more interested in trying an e-cigarette offered by a friend if it was flavored like fruit, candy or menthol rather than tobacco or alcohol.¹⁰

The study was cited by the Robert Wood Johnson Foundation (RWJF) in its comment submission to FDA as a reason for developing a rule requiring manufacturers to demonstrate that specific flavors help smokers quit or switch entirely to e-cigarettes and that the benefits outweigh any potential harms from youth initiation.¹¹ The study is also regularly cited by the Campaign for Tobacco-Free Kids as a reason to withdraw flavored e-cigarettes from the market.

¹⁰ Pepper, J. K., K. M. Ribisl and N. T. Brewer. "Adolescents' interest in trying flavoured e-cigarettes." *Tobacco Control*. September 15, 2016.
http://tobaccocontrol.bmj.com/content/tobaccocontrol/25/Suppl_2/ii62.full.pdf

¹¹ Robert Wood Johnson Foundation. "Comments from Richard Besser, MD, on Advanced Notice of Proposed Rulemaking on Regulation of Flavors in Tobacco Products." July 12, 2018.
<https://www.rwjf.org/en/library/articles-and-news/2018/07/comments-from-richard-besser-on-advanced-notice-of-proposed-rulemaking-on-regulation-of-flavors-in-tobacco-products.html>



Of the teens who had never used e-cigarettes, only 1.7% expressed an interest and of those who had never smoked cigarettes the number was 3.3%.



What isn't highlighted by the study's authors or the RWJF, however, is the total percentage of teens who expressed an interest in trying e-cigarettes of any and all flavors. Just 7.4% of those surveyed said they would be interested. Of the teens who had never used e-cigarettes, only 1.7% expressed an interest and of those who had never smoked cigarettes the number was 3.3%. Furthermore, 5.2% of the study's participants were current vapers, and 3.6% were current smokers. An earlier study conducted by the same author assessing the willingness to try e-cigarettes among teenage males found only 18% were willing to even try an e-cigarette while "willingness to try plain versus flavored varieties did not differ."¹²

In fact, another survey shows that nonsmoking teens' interest in e-cigarette flavors is negligible. A 2015 survey of nonsmoking teens aged 13-17 found interest levels in flavored e-cigarettes of 0.4 out of a possible score of 10.¹³

When assessing non-smoking teens, flavors are often not the leading reason for e-cigarette experimentation. A 2016 study using longitudinal surveys of middle and high school students in Connecticut from fall 2013 (Wave 1) to spring 2014 (Wave 2)¹⁴ found the most commonly reported reason was "curiosity" (reported by 57.1% of respondents). The second most-reported reason was "good flavors" (reported by 41.8% of respondents). All students at Wave 1 had used an e-cigarette, and the students were asked to endorse as many as 11 possible reasons for use. But as well as examining reasons for use, the study's authors

¹² Pepper, Jessica K et al. "Adolescent males' awareness of and willingness to try electronic cigarettes" *Journal of Adolescent Health* vol. 52, 2012. 144-50. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3569032/>

¹³ Shiffman, Saul et al. "The impact of flavor descriptors on nonsmoking teens' and adult smokers' interest in electronic cigarettes." *Nicotine and Tobacco Research*. October, 2015. <http://www.ncbi.nlm.nih.gov/pubmed/25566782>.

¹⁴ Bold, Krysten W. et al. "Reasons for Trying E-cigarettes and Risk of Continued Use." *Pediatrics* vol 138, September, 2016. <http://pediatrics.aappublications.org/content/early/2016/08/04/peds.2016-0895>

examined predictors of continued e-cigarette use at Wave 2. “The ‘good flavors’ response was not a significant predictor of either continued use or more frequent use of e-cigarettes at Wave 2,” said the authors.



Rather, the most robust predictor of continued e-cigarette use at Wave 2 was whether the participant was trying to quit smoking.



Rather, the most robust predictor of continued e-cigarette use at Wave 2 was whether the participant was trying to quit smoking. Furthermore, once cigarette smoking status was taken into account, “good flavors, can hide from adults, and healthier than regular cigarettes no longer predicted continued e-cigarette use; these reasons were endorsed more often by current cigarette smokers.”

In their ANPRM comment to FDA, the tobacco company Altria Client Services examined Wave 1 youth data from the PATH survey to see if there was a relationship between the flavor of the first product tried and subsequent use after initial trial. Altria’s analysis found that 74% of youth who had “ever tried” an e-cigarette or smokeless tobacco product and whose first use was flavored were either not using these products or met PATH’s definition of “very light” consumer. Analyzing the longitudinal data on those who had never used a tobacco product at Wave 1 but had used an e-cigarette by Wave 2, first trial of a flavored or a non-flavored e-cigarette did not differentially impact youth becoming “not light” consumers.

Flavors can appeal to both adults and minors for a variety of reasons, and it is extremely difficult to delineate what kinds of flavors will appeal to adults but not appeal to youth. But on the basis of the evidence, as it stands, the claim that e-cigarette flavors of the sweet or fruit varieties present an especially appealing proposition to youth is not borne out by the available data.

Most youth e-cigarette use is occasional and experimental. There is no empirical evidence that e-cigarette manufacturers produce flavors specifically designed to appeal to children. This should not be surprising as such a strategy would be unethical and a poor business strategy. There is little incentive for e-cigarette producers to risk the ire of parents and

regulators by appealing to cash-poor teens when there is a lucrative market of more than 30 million adult smokers.

Developing a product standard requiring e-cigarette manufacturers to demonstrate that a specific flavor will both appeal to and assist smokers in switching to e-cigarettes while presenting no appeal to any youth would be both unrealistic and counterproductive. There is also no reason to think banning flavors would reduce youth e-cigarette use as youth who experiment with flavored e-cigarettes could just as plausibly experiment tobacco flavored e-cigarettes or even combustible cigarettes.



There is also no reason to think banning flavors would reduce youth e-cigarette use as youth who experiment with flavored e-cigarettes could just as plausibly experiment with smokeless tobacco and unflavored e-cigarettes or even combustible cigarettes.



Curiosity and experimentation are key factors when examining reasons for the use of many consumer products, especially with novel products such as e-cigarettes. The most likely explanation for youth e-cigarette use is not that flavors cause e-cigarette use but that those who do use e-cigarettes prefer flavors to non-flavors. This is typical preference ordering.¹⁵ There will always be a favorite category or flavor among this demographic so whichever one it is will be presented as problematic.

If a tobacco-flavored e-cigarette were the most popular, there would be even more opposition to e-cigarettes for creating a cleaner tobacco taste and “re-normalizing” tobacco use. There is no evidence to suggest the absence of non-tobacco flavors would affect consumption. The assumption is that if people’s preferred option of a product were not available, they wouldn’t use the product at all. This is unrealistic and fails to account for the various dynamics that lead to illicit youth use of adult products.

¹⁵ Phillips, Carl V. “Banning Flavors: The Core Argument is Based on Gaslighting, Not Evidence.” Daily Caller. July 20, 2018. <https://dailycaller.com/2018/07/20/banning-flavors-the-core-argument-is-based-on-gaslighting-not-evidence/>

PART 3

E-CIGARETTE FLAVORS AND THE “GATEWAY EFFECT”

Critics of e-cigarettes as a harm reduction tool warn youth use of these products can progress to cigarette use, and posit e-cigarettes as the causal mechanism for such a progression. This so-called “gateway effect” has elicited much comment due to several studies showing that teens who initiate e-cigarette use, later use combustible cigarettes.¹⁶ The gateway effect is a popular concept and has long been an argument for the continued prohibition of illicit drugs such as marijuana.¹⁷

But just because someone tries a product, even one with addictive properties, does not mean the use of this product causes that person to try another, more harmful product. While e-cigarette use may be associated with cigarette use in some adolescents, it is nearly

¹⁶ Bold, Krysten W. et al. “Trajectories of E-Cigarette and Conventional Cigarette Use Among Youth.” *Pediatrics*. December, 2017. <http://pediatrics.aappublications.org/content/pediatrics/141/1/e20171832.full.pdf>

¹⁷ Morris, Julian. “The Gateway Effect of Marijuana.” Reason Foundation. May 2018. <https://reason.org/wp-content/uploads/2018/05/gateway-effect-of-marijuana.pdf>

impossible to discern a causal link. However, this is not to rule out the possibility that e-cigarette use has or will never cause someone to take up smoking.

When discussing the possibility of a gateway, researchers are often unclear as to how they define a gateway. But this paper regards it as the typical claim that exposure to a product causes the use of another. For example, a young person who would not otherwise smoke cigarettes starts smoking due to use of e-cigarettes.¹⁸ Researchers have yet to define what exposure is necessary to cause passage through this gateway and what is the magnitude of this effect.

In a population of many millions of youth who have tried e-cigarettes, it is extremely unlikely there has never been a single case of a non-smoking youth who has developed a cigarette smoking habit due to their initial use of an e-cigarette. If this effect is of a large enough magnitude, there could be net public health negative consequences from the availability of e-cigarettes. But when we consider the magnitude of the benefits adult smokers gain by switching to e-cigarettes the evidence to justify any action that could limit their availability must be sound.

To examine whether this gateway hypothesis is correct, we would need to know how many young people would not otherwise have smoked, but due to vaping transition to smoking. We would in effect, need to know what would have happened in the absence of e-cigarettes. Asserting that this may have happened to at least one person or an unspecified number of young people is not justification for a generalized claim that e-cigarettes are a gateway to smoking. In fact, on the population level, we see that as e-cigarette use has increased, cigarette smoking has decreased among high school students.



In fact, on the population level, we see that as e-cigarette use has increased, cigarette smoking has decreased among high school students.



¹⁸ Bates, Clive. "How not to be duped by gateway effect claims." The Counterfactual. June 10, 2016. <https://www.clivebates.com/how-not-to-be-duped-by-gateway-effect-claims/>

Seven years of data from the Centers for Disease Control and Prevention show a consistent trend of declining high school and middle school smoking rates whether adolescent vaping is up, down or flat.¹⁹ In 2017, the high school smoking rate fell to the lowest level on record—7.6%—compared to 15.8% in 2011. As for e-cigarettes use, after several years of substantial increases, there was a 30% decline between 2015 and 2016. Current high school e-cigarette use was 11.7% in 2017, substantially down from its high point of 16% in 2015. Adolescent cigar, waterpipe, and pipe tobacco smoking also declined. In fact, according to the University of Michigan Monitoring the Future survey, the rate of decline in adolescent smoking since 2010 is four times greater than it was between 1975 and 2010.²⁰

These figures by themselves do not completely disprove a gateway effect. Some may argue the decline in smoking would have been faster without e-cigarettes but given the rate of decline since 2010 this appears unlikely. It should give researchers pause as to why the declines in teen cigarette smoking have been so pronounced at the same time as e-cigarettes grew in popularity.



It should give researchers pause as to why the declines in teen cigarette smoking have been so pronounced at the same time as e-cigarettes grew in popularity.



It is also crucial that researchers define what they mean by smoking and vaping. If ever having used an e-cigarette or cigarette is the criterion being used, this is of little importance. What matters is whether a high schooler develops a sustained smoking or vaping habit; otherwise researchers are simply measuring experimentation.

While it is true that an association between vaping and smoking may be indicative of a gateway, there could also be “reverse causation,” whereby young smokers vape because they are trying to quit or reduce cigarette consumption, therefore causing an association or

¹⁹ “Youth Tobacco Use.” Centers for Disease Control and Prevention. https://www.cdc.gov/tobacco/data_statistics/fact_sheets/youth_data/tobacco_use/index.htm

²⁰ Bates, Clive. “Trends in tobacco and nicotine use in the United States.” The Counterfactual. April, 2018. <https://www.clivebates.com/documents/USTrendsApril2018.pdf>

that the same inclinations that drive some teens to vape drive those same teens to smoke tobacco. This would be an example of “common liability.” It is incredibly difficult to account for common liability in tobacco gateway studies, and none have managed to do so adequately. This leads to a situation where gateway studies conclude that people who are willing to try one tobacco or nicotine product are more willing to try another than those who have never tried any tobacco product, which is trivially true.

Some studies attempt to correct for common liability by trying to assess how susceptible people are to smoking and vaping. But these measures of susceptibility come woefully short of accounting for common liability. Many researchers, as opposed to the media reporting of their research, do however make clear that they cannot prove causation.

A 2015 study on school students in Los Angeles found those who use e-cigarettes are 2.7 times more likely to report using conventional tobacco over the next year.²¹ But the study’s authors concede they “cannot conclude that e-cigarette use directly leads to smoking.”

Assessing the state of the evidence on adolescents and e-cigarette use, Kozlowski and Warner conclude the available studies at best support the view “that a minority of the relatively small number of e-cigarette triers—who haven’t also been experimenting with other tobacco products already—will go on to some experimentation with cigarettes.”²²

The critical question surrounding a possible gateway is, why would someone using a low-risk product, who chose not to use a high-risk product, then transition to the high-risk product? Intuitively, it would be strange for a non-smoking youth to experiment with flavored e-cigarettes and progress to a much more harmful form of nicotine consumption in a flavor such as tobacco that they previously refused to try in its much less harmful form.

Much has also been made of the National Academies of Sciences Engineering and Medicine (NASSEM) report on the public health consequences of e-cigarettes, which concludes there is “substantial evidence that e-cigarette use increases risk of ever using combustible tobacco

²¹ Leventhal, Adam M. et al. “Association of Electronic Cigarette Use With Initiation of Combustible Tobacco Product Smoking in Early Adolescence.” *Journal of the American Medical Association*. August 13, 2015. <https://jamanetwork.com/journals/jama/fullarticle/2428954>

²² T. Kozlowski, Lynn and Kenneth E. Warner. “Adolescents and e-cigarettes: Objects of concern may appear larger than they are.” *Drug and Alcohol Dependence*. May 1, 2017. <http://www.sciencedirect.com/science/article/pii/S0376871617300236?showall%3Dtrue%26via%3Dihub>

cigarettes among youth and young adults.”²³ This has been taken to mean e-cigarettes are a gateway product to cigarette smoking.

Scott Gottlieb and Secretary of Health and Human Services Alex M. Azar raised the NASEM report in an op-ed for the *Washington Post*, warning of the dangers of e-cigarettes pose to children, which could easily be misinterpreted as arguing for a gateway effect.²⁴ However, according to Dr. Nancy A. Rigotti of Harvard Medical School and Massachusetts General Hospital, who was on the committee for the NASEM review, this is a misinterpretation of what the review was trying to communicate. Speaking to a conference on April 30, 2017, Rigotti said: “what we are not actually saying here is that it leads to young youth smoking, something that has been sometimes lost in translation.”²⁵ Dr. Rigotti clarified that there is an “enormous amount of ecological data” showing that as youth vaping increased cigarette smoking decreased, which makes it “hard to argue that there is a gateway there.”

Considering the vast majority of adolescent e-cigarette users are current or former tobacco users, there is little reason to think e-cigarette flavors are in and of themselves especially appealing to teens with no history or propensity toward tobacco use and even less to believe they are acting as a gateway to smoking. Causation can never be proved 100% in gateway studies but can be reasonably inferred. Unfortunately, it is nearly impossible to discern a tiny gateway effect from zero.

For now, though, flavored or not, there is no evidence to date suggesting e-cigarettes are a gateway to smoking in the way the theory's advocates describe. Any study attempting to establish a gateway from e-cigarette use to cigarette smoking must adequately account for both reverse causation and common liability. None thus far have done so. In an extensive

²³ National Academies of Sciences, Engineering, and Medicine. “Public Health Consequences of E-Cigarettes.” Washington, DC: The National Academies Press. January 23, 2018. <https://doi.org/10.17226/24952>.

²⁴ Azar M. and Scott Gottlieb. “We cannot let e-cigarettes become an on-ramp for teenage addiction.” *Washington Post*. October 11, 2018. https://www.washingtonpost.com/opinions/we-cannot-let-e-cigarettes-become-an-on-ramp-for-teenage-addiction/2018/10/11/55ce424e-ccc6-11e8-a360-85875bac0b1f_story.html?noredirect=on&utm_term=.8bd689113383

²⁵ Rigotti, Nancy A. “The National Academies of Science, Engineering and Medicine Report on E-Cigarettes – Summary and Relevance to Clinicians.” E-cigarette Summit. April 30, 2018. <https://vimeo.com/268310971>

paper, Carl V. Phillips explains how researchers can conduct valid gateway research and explains where current studies have gone wrong.²⁶

3.1

A YOUTH VAPING EPIDEMIC?

In September 2018, Commissioner Gottlieb announced that new FDA data showed youth e-cigarette use had reached epidemic levels. Gottlieb later revealed that unpublished data from the National Youth Tobacco Survey showed a 77% increase in current high school e-cigarette use in 2017-2018. If this is true, it would mean past-30 day use vaping among high school students rose from 11.7% to around 20%.²⁷

In response to these findings, Gottlieb asked the country's five largest e-cigarette manufacturers to submit plans to combat youth use. If these plans do not satisfy the FDA, all non-tobacco e-cigarette flavors could be withdrawn from the market, and the Deeming Rule could be implemented in full before the current deadline if 2022. Online sales of e-cigarettes could also be prohibited.



In response to these findings, Gottlieb asked the country's five largest e-cigarette manufacturers to submit plans to combat youth use.



Even if the data Gottlieb cited is accurate, is he right to classify current youth e-cigarette use of 20% as an epidemic? For context, current youth alcohol use in 2017 was 29.8%, marijuana use was 19.8%, and 28.7% of teens were sexually active. If 20% of high school students vaping at least once in the past 30 days rises to the status of an epidemic, would it be accurate to say there are also epidemics of teenage sex, alcohol and marijuana use? The answer is clearly no.

²⁶ Phillips, Carl V. "Gateway Effects: Why the Cited Evidence Does Not Support Their Existence for Low-Risk Tobacco Products (and What Evidence Would)." *International Journal of Environmental Research and Public Health*. May 21, 2015. <https://www.mdpi.com/1660-4601/12/5/5439/htm>

²⁷ Sullum, Jacob. "FDA Is Ready to Restrict E-Cigarettes Based on Data We're Not Allowed to See." *Reason.com*. October 24, 2018. <https://reason.com/blog/2018/10/24/fda-is-ready-to-restrict-e-cigarettes-ba>

If the FDA numbers are correct, youth vaping has risen substantially following a flat line and a previous 30% drop to reach a level four percentage points higher than it was in 2015.

Of course, a sudden and substantial rise in youth vaping should be taken seriously, but there are a number of factors that need to be taken into account before hyperbolic language is thrown into the mix. As noted previously, it is important to distinguish between current use, frequent use, and daily use when assessing the scale of the problem and any potential harm being done to developing adolescent brains. Using an e-cigarette once in the past 30 days is no indicator of addiction. Although by no means perfect, frequent or daily use are better indicators of a potential problem. Taking the year 2015, when youth vaping was at its highest before the 2018 data, only 1.7% of high school students reported vaping on 20 or more days in the previous month, and 1.1% reported vaping on a daily basis.

According to a study of the 2015 National Youth Tobacco Survey, 0.3% of youth who had never smoked cigarettes were frequent vapers, and 0.2% were daily vapers.²⁸ “Although there is reasonable concern about the recent increase in ever and past 30-day e-cigarette among youth, the data reported here show that the majority of e-cigarette use is experimental or infrequent, while regular use is minimal, among never smokers,” said the study’s authors.



E-cigarettes are a harm reduction product and radically different from combustible cigarettes, which do indeed cause death and disease. To describe an increase in past 30-day use of these products as an epidemic is grossly irresponsible.



Gottlieb’s description of youth vaping as an epidemic also fails to take into account substantial declines in teen smoking and examining e-cigarettes in the full context of declining combustible tobacco use. E-cigarettes are a harm reduction product and radically

²⁸ Farsalinos, Konstantinos, Venera Tomaselli, and Riccardo Polosa. “Frequency of Use and Smoking Status of U.S. Adolescent E-Cigarette Users in 2015.” *American Journal of Preventive Medicine*. June, 2018. <https://www.ncbi.nlm.nih.gov/pubmed/29631871>

different from combustible cigarettes, which do indeed cause death and disease. To describe an increase in past 30-day use of these products as an epidemic is grossly irresponsible.

While reasonable measures should be taken to restrict youth access to e-cigarettes, prohibiting the largest category of e-cigarette products with adults—flavors—on the basis of one year’s worth of data showing an increase in current youth use is unjustifiable. It is equally unjustifiable to engage in policy-making that will affect millions of adult consumers trying to quit cigarettes on the basis of data that has not been made available to the public. The correct course of action would have been for Gottlieb to wait until the full data are released publicly so as to engage in reasonable dialogue with industry and advocacy groups. Threatening the near destruction of an industry based on unpublished data is no way to make rational policy.

PART 4

E-CIGARETTE FLAVORS, SWITCHING, AND SMOKING CESSATION

Many non-vapers are mystified as to why adult smokers would be drawn to sweet or dessert-flavored e-cigarettes if they are hoping to transition away from smoking cigarettes. Surely vapers would prefer to use a product that closely mimics the taste of their preferred cigarette as well as delivering nicotine? The reasons for adult use of these flavors will be covered later in this section, but suffice to say adult smokers trying to switch away from cigarettes do find these products appealing as do long-term vapers. In fact, the data show that for many years non-tobacco flavors have been popular with adult e-cigarette users.

According to the former surgeon general's report, the use of flavored e-cigarettes was highest among young adults, according to the 2013–2014 National Adult Tobacco Survey data. Among those who reported using e-cigarettes every day or some days, 91.6% of young adults (18–24 years old) reported using an e-cigarette flavored to taste like menthol, mint, clover, spice, candy, fruit, chocolate, or other sweets.²⁹

²⁹ Centers for Disease Control and Prevention. "National Adult Tobacco Survey." Last updated October 19, 2017. https://www.cdc.gov/tobacco/data_statistics/surveys/nats/index.htm

On the other hand, 66.6% of adults over the age of 25 who reported using e-cigarettes every day or some days had used flavored e-cigarettes. Tobacco Control campaigners often conflate young adults with minors in discussions about the potential risks of flavors. This is deeply misleading. Young adults are adults. When assessing the role that reduced risk products like e-cigarettes can play in diminishing the prevalence of smoking-related disease, it is important that all smokers, including those aged 18-25, have access to these products. It is vitally important for young adult smokers to have access to these products as they provide an early off-ramp from smoking. Even from some of the earliest data on e-cigarette use, we see that non-tobacco flavors are extremely popular with adult consumers.



Young adults are adults. When assessing the role that reduced risk products like e-cigarettes can play in diminishing the prevalence of smoking-related disease, it is important that all smokers, including those aged 18-25, have access to these products.



A systematic review of consumer preference for e-cigarette attributes including flavors, found that both young adults and adults over the age of 25 preferred sweet flavors.³⁰ This runs counter to the view that sweet or other non-tobacco e-cigarette flavors are designed to and are solely appealing to youth. Indeed, many adult vapers directly attribute their success in quitting smoking to the availability of e-cigarette flavors. Commissioner Gottlieb has acknowledged the importance of these stories.³¹

³⁰ Zare, Samane, Mehdi Nemati and Yuqing Zheng. "A systematic review of consumer preference for e-cigarette attributes: Flavor, nicotine strength, and type." *PLOS One*. March 15, 2018. <http://journals.plos.org/plosone/article?id=10.1371/journal.pone.0194145>

³¹ Gottlieb, Scott. "Nicotine and the Role of Science in Regulation." Society for Research on Nicotine and Tobacco (SRNT). Baltimore, MD. February 23, 2018. <https://www.fda.gov/NewsEvents/Speeches/ucm598073.htm>

A 2013 study of dedicated, long-term vapers showed flavors “appear to contribute to both perceived pleasure and the effort to reduce cigarette consumption or quit smoking.”³² Published in the *International Journal of Environmental Research and Public Health*, the study found e-cigarette users typically preferred tobacco flavors when initially switching from cigarettes to e-cigarettes. Longer term ex-smokers actually showed a preference for non-tobacco flavors. Respondents showed substantial heterogeneity of flavor preference, often switching between flavors, with former cigarette smokers switching more frequently than current smokers. Almost three-quarters of respondents said they liked a variety of flavor choices.

Almost 70% of the respondents said flavor variety was “very important” in their efforts to quit or reduce smoking and that removing flavor options would reduce the enjoyment of vaping. Nearly half said banning flavors would increase their cravings for cigarettes and 40% said it would lessen their chances of reducing or quitting smoking. The number of e-cigarette flavors regularly used was also independently associated with smoking abstinence.



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Demand for varieties of flavors and nicotine strengths are reflected among e-cigarette users across the world. A 2016 analysis of European and South Korean e-cigarette users showed 28% for tobacco flavors, 23% for fruits and 20% for botanicals.³³ In the U.S., a survey conducted by the Consumer Advocates for Smoke-Free Alternatives Association in 2015 examined 343 adult e-cigarette users. More than 70% of those surveyed “credit[ed] interesting flavors with helping them quit.”³⁴

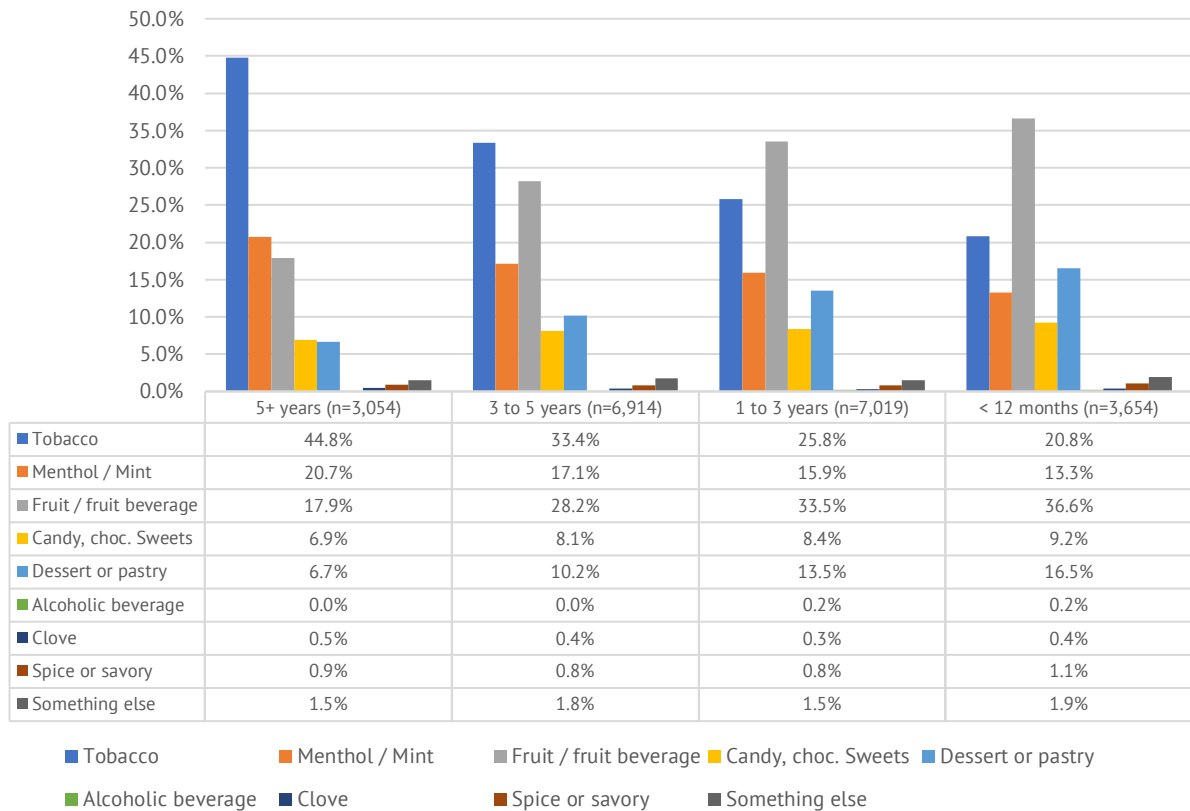
³² Farsalinos, Konstantinos et al. “Impact of Flavour Variability on Electronic Cigarette Use Experience: An Internet Survey.” *International Journal of Environmental Research and Public Health*. December 17, 2013. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3881166/>

³³ EY. “E-cigarettes: An emerging category.” May, 2016. <https://www.ey.com/Publication/vwLUAssets/E-cigarettes-an-emerging-category/%24FILE/EY-E-Cigarette-report.pdf>

³⁴ Phillips, Carl V. “CASAA ecig survey results.” Consumer Advocates for Smoke-free Alternatives Association. January 4, 2016. <https://casaa.org/wp-content/uploads/CASAA-Vaping-Survey-Results-CVP-post-4-January-2016.pdf>

More recent analysis confirms these patterns, with long-term switchers initially preferring tobacco flavors and more recent switchers preferring fruit and dessert flavors. A study published in 2018 examined 20,836 adults in the U.S. who were using e-cigarettes on a frequent basis, of whom 75.9% had completely switched from cigarettes to e-cigarettes.³⁵ The study represents one of the largest academic surveys of adult vapers ever conducted. It found frequent e-cigarette users are now most likely to have started vaping with products flavored to taste like fruit or a fruit drink and are increasingly likely to have started vaping with dessert or pastry flavors.

FIGURE 1: FLAVOR OF FIRST E-CIGARETTE PURCHASED BY TIME SINCE FIRST E-CIGARETTE PURCHASE: FREQUENT E-CIGARETTE USERS

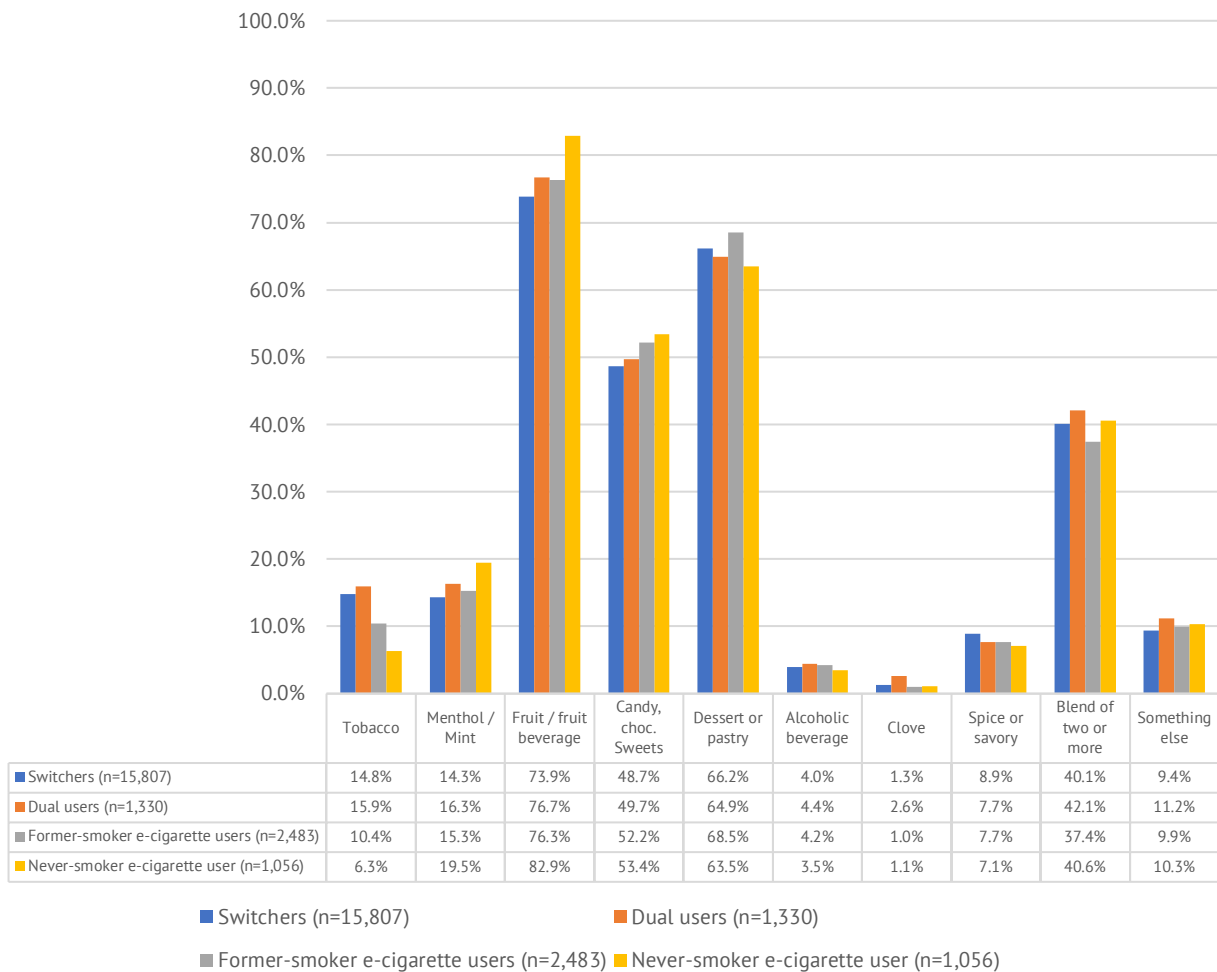


Source: Russell, Christopher, Neil McKeganey, Tiffany Dickson, Mitchell Nides. “Changing patterns of first e-cigarette flavor used and current flavors used by 20,836 adult frequent e-cigarette users in the USA.” *Harm Reduction Journal*. April 18, 2018.

³⁵ Russell, Christopher, Neil McKeganey, Tiffany Dickson and Mitchell Nides. “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*. April 18, 2018. <https://harmreductionjournal.biomedcentral.com/articles/10.1186/s12954-018-0238-6>

“Between 2011 and 2016, the proportion of first e-cigarette purchases that were flavored to taste like a fruit had almost doubled, while tobacco-flavored first e-cigarette purchases had almost halved,” said the study’s authors. “These data suggest a transition in flavor preference at e-cigarette use initiation over time, from tobacco to non-tobacco flavors, which is consistent with data from a U.S. nationally representative survey that found both former-smoking exclusive e-cigarette users and dual users reported significantly higher rates of current use of a non-tobacco-flavor—72.5% and 72.9%, respectively—compared to initiation.”

FIGURE 2: E-CIGARETTE/E-LIQUID FLAVORS CURRENTLY USED BY 20,676 U.S. ADULT FREQUENT E-CIGARETTE USERS, STRATIFIED BY TOBACCO USE PATHWAY(TUP) GROUP



Source: Russell, Christopher, Neil McKeganey, Tiffany Dickson, Mitchell Nides. “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*. April 18, 2018.

Among participants, current e-cigarette use was dominated by fruit/fruit beverage, dessert/pastry, and/or candy/chocolate/sweets flavors. The trend toward sweet flavors is demonstrated in the chart below, which shows that tobacco/menthol flavors, which were once the most popular first flavors for switchers and dual users, currently rank as the 5th and 6th most popular flavors.

According to the study's authors, restricting the availability of non-tobacco flavors could reduce adult smokers' interest in switching to e-cigarettes and raises the possibility that current e-cigarette users could return to combustible cigarette smoking, which is vastly more harmful to health.

This is in concurrence with a recent study published in *Tobacco Control* which examined the possible impact of a ban on all flavored tobacco products, including e-cigarettes. The study concluded such a ban would "likely reduce the smoking/vaping rates, but the use of cigarettes would be higher than in the status quo."³⁶ Consumers of e-cigarettes, not the manufacturers, are the primary drivers of the variety of flavors and nicotine strengths seen in the e-cigarette market.

More recently, in response to FDA's ANPRM on the regulation of flavored tobacco products, Dr. Konstantinos Farsalinos and Dr. Christopher Russell conducted the largest ever survey of established U.S. vapers.³⁷ The study sample consisted of individuals aged 18 and older who have ever used an e-cigarette, and concluded:

Non-tobacco flavors, especially fruit and dessert/pastry/bakery flavors, are the most prevalent choices of the adult established, dedicated US e-cigarette users who participated to this study. They are particularly popular not only during long-term e-cigarette use but also at the period of e-cigarette use initiation.

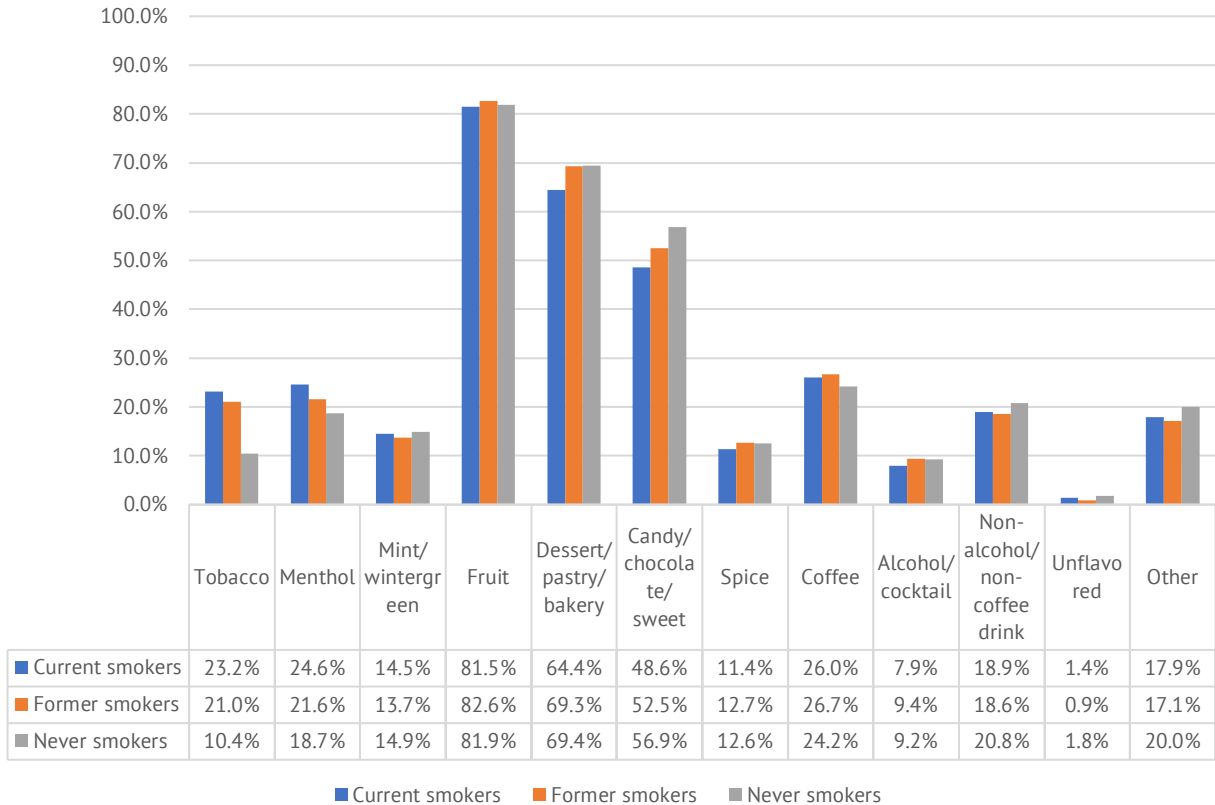
The study sample consisted of 69,233 adult e-cigarette users living in the U.S. Almost 95% of participants reported that they were ever smokers. The majority had quit smoking, while

³⁶ Buckell, John, Joachim Marti and Jody L. Sindelar. "Should flavours be banned in cigarettes and e-cigarettes? Evidence on adult smokers and recent quitters from a discrete choice experiment." *Tobacco Control*. 28 May, 2018. <http://tobaccocontrol.bmj.com/content/early/2018/05/28/tobaccocontrol-2017-054165>

³⁷ Farsalinos, Konstantinos. "Submitting to the FDA the findings of the largest ever survey on e-cigarette flavors use by US vapers." E-cigarette Research. August 11, 2018. <http://www.ecigarette-research.org/research/index.php/whats-new/2018-2/266-us-flav>

61% of current smokers were occasional smokers (smoking on some days). Only 5.2% of the study sample reported being never smokers. Almost 92% of former smokers reported that they were using e-cigarettes at the time of quitting.

FIGURE 3: CHOICE OF FLAVORS AT E-CIGARETTE USE INITIATION AMONG CURRENT SMOKERS, FORMER SMOKERS AND NEVER SMOKERS



Source: Farsalinos, Konstantinos, Christopher Russell, George Lagoumintzis, Konstantinos Poulas. “Patterns of flavored e-cigarette use among adults vapers in the United States: an internet Survey.”

The study’s principal findings are that fruit and dessert/pastry/bakery flavors are the most common choices of established, dedicated adult e-cigarette users who participated in this study. Crucially, these flavors were not just popular during long-term e-cigarette use but also at the period of e-cigarette use initiation. This suggests that non-tobacco flavors are increasingly important for smokers making the initial switch away from cigarettes as well as maintaining cigarette abstinence. The survey participants also considered the availability of fruit and dessert/pastry/bakery flavors particularly important in their effort to quit smoking and to prevent relapse to smoking.

The e-cigarette manufacturer Juul Labs has received a barrage of media criticism over the alleged popularity of their product among youth. Juul has been criticized both for the nicotine strength of their product and flavor varieties such as “fruit medley” and “creme brulee.” What hasn’t received so much attention is a study of 19,000 Juul users examining transitions in cigarette smoking associated with Juul use.

Eighty-seven percent were current or former smokers when they first started using Juul, and of those who were smoking when they first started vaping, 64% were no longer smoking. More than three-quarters of respondents attributed their smoking cessation to Juul.³⁸ Furthermore, 56% of Juul users who were still smoking reported they had reduced their daily cigarette consumption by more than 50%.



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Considering that dual use is often the first stage on the road to smoking cessation, these results are extremely encouraging. Just 8% of respondents who were former smokers when they started using Juul relapsed to smoking. “In total, the number of smokers who quit after using Juul was 137 times the number of never-smokers who started smoking and 21 times the number of former smokers who relapsed,” writes Reason’s Jacob Sullum.³⁹ Even accounting for sampling bias, these results should be taken into account when assessing the possible impact of a tobacco product standard limiting e-cigarette flavor choice.

Furthermore, there are at present two longitudinal studies that suggest e-cigarette flavors play a positive role in smoking cessation. Using the PATH data on young adult smokers and current e-cigarette users, Dr. Julia Chen shows that vapers who used one or more non-

³⁸ Russell, Christopher, Neil McKeganey and Farhana Haseen. “Transitions in Cigarette Smoking Associated with Use of the Juul Vaping Device Among 18,799 Adults in the United States.” Centre for Substance Use Research. June 28, 2018. <http://csures.com/wp-content/uploads/2018/07/Russell-et-al-2018-Smoking-Transitions-Among-Adult-JUUL-Users.pdf>

³⁹ Sullum, Jacob. “Survey of Juul Customers Shows Many Vapers Stop Smoking.” Reason.com. July 2, 2018. <http://reason.com/blog/2018/07/02/survey-of-juul-customers-suggests-many-v>

tobacco flavors were much more likely to have reduced or quit smoking than non-e-cigarette users.⁴⁰ The second study by Buu et al. found that non-tobacco flavored e-cigarettes were positively associated with a lower quantity of cigarettes smoked over time.⁴¹ The National Academies of Sciences, Engineering, and Medicine (NASEM),⁴² the American Cancer Society (ACS),⁴³ Royal College of Physicians (RCP),⁴⁴ Public Health England (PHE),⁴⁵ and Scott Gottlieb all agree that smokers who switch exclusively to e-cigarettes dramatically reduce their risk of smoking-related disease. E-cigarettes have the potential to save millions of lives if they are allowed to thrive in a competitive marketplace with a variety of product types and flavors.



Clearly, the available scientific evidence demonstrates that, instead of presenting a net public health harm, flavored e-cigarettes are a net benefit to public health, and attempts to severely restrict or prohibit non-tobacco e-cigarette flavors will undermine tobacco harm reduction efforts.



⁴⁰ Chen, J. C. “Flavored E-cigarette Use and Cigarette Smoking Reduction and Cessation-A Large National Study among Young Adult Smokers.” *Substance Use & Misuse*. October, 2018. <https://www.ncbi.nlm.nih.gov/pubmed/29624135>

⁴¹ Buu A, Y. H. Hu, M. E. Piper and H.C. Lin. “The association between e-cigarette use characteristics and combustible cigarette consumption and dependence symptoms: Results from a national longitudinal study.” *Addiction Behaviors*. April 2018. <https://www.ncbi.nlm.nih.gov/pubmed/29627636>

⁴² National Academies of Sciences, Engineering and Medicine. “Public Health Consequences of E-cigarettes.” January 23, 2017. <http://nationalacademies.org/hmd/Reports/2018/public-health-consequences-of-e-cigarettes.aspx>

⁴³ Douglas, Clifford E. “The American Cancer Society public health statement on eliminating combustible tobacco use in the United States.” June 11, 2018. <https://onlinelibrary.wiley.com/doi/full/10.3322/caac.21455>

⁴⁴ Amos, Amanda et al. “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>

⁴⁵ Public Health England. “E-cigarettes: an evidence update.” August 19, 2015. <https://www.gov.uk/government/news/e-cigarettes-around-95-less-harmful-than-tobacco-estimates-landmark-review>

Clearly, the available scientific evidence demonstrates that, instead of presenting a net public health harm, flavored e-cigarettes are a net benefit to public health, and attempts to severely restrict or prohibit non-tobacco e-cigarette flavors will undermine tobacco harm reduction efforts, degrading the appeal of e-cigarettes and possibly resulting in a black market for flavored e-liquids.

The availability and variety of flavors contribute to increasing the appeal of e-cigarettes relative to combustible cigarettes. Since e-cigarettes are estimated to be 95%-99% safer than combustible cigarettes, these adult preferences must be taken into account when considering current patterns of use in terms of avoiding cigarette smoking relapse and the decision to switch to e-cigarettes in the first place.

PART 5

TOXICITY

Concerns have been raised over potential differences in the toxicity of flavored e-cigarette products compared with non-flavored or tobacco-flavored e-cigarettes. But these concerns should be considered within the broader context of the differential risks between a flavored e-cigarette product and a combustible cigarette. The presence of a hazardous agent in a flavored e-cigarette product does not mean the product presents an unacceptable level of risk.

The dosage of harmful and potentially harmful chemicals is the central factor in assessing toxicological risk, and this dosage must always be compared to the relevant alternative, which is combustible cigarettes. Studies attempting to analyze the toxicity of flavored e-cigarette products must reflect how consumers actually use the product in the real world. It is the responsibility of e-cigarette manufacturers to ensure their products are as safe as possible. But completely removing non-tobacco flavor constituents from e-cigarettes risks degrading the product to such an extent that many e-cigarette users may revert to smoking.⁴⁶

⁴⁶ Wade, Carrie L and Clive Bates. "Think before you ban: The awkward case for e-cigarette flavor bans." R Street Institute No. 144. June, 2018. <https://2o9ub0417chl2lg6m43em6psi2i-wpengine.netdna-ssl.com/wp-content/uploads/2018/06/144.pdf>

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The FDA is right to be concerned with the lack of widely recognized product standards among e-cigarette manufacturers, which can lead to mislabeling and confused or ill-informed consumers. Efforts should be made both among industry actors and FDA to develop product standards that would limit e-cigarette users' exposure to harmful or potentially harmful chemicals while ensuring the user experience is not degraded.

PART 6

CONSUMER SURPLUS

Consumer surplus is defined as the difference between the total amount that consumers are willing to pay for a product and the price they actually pay. Without measuring consumer surplus, regulators cannot capture the benefits consumers derive from a particular product including pleasure.

In the ANPRM regarding the possible introduction of a product standard limiting levels of nicotine in combustible cigarettes, FDA asked: “How should potential consumer surplus or utility loss from the removal of nicotine in cigarettes be considered, given the availability of other sources of nicotine such as ENDS and the continued availability of combustible tobacco products?”

Although no such question was present in the ANPRM regarding flavored tobacco products, consumer surplus is an essential part of any analysis of developing a product standard that could limit or prohibit non-tobacco e-cigarette flavors. The necessity of such analysis cannot be overstated.

“The consumer’s surplus is the most crucial concept in the measurement of social benefits in any social cost-benefit calculation,” wrote the welfare economist E.J. Mishan. In the case of combustible cigarettes, much of the public health literature ignores consumer surplus, asserting that smoking is an involuntary disease that presents only costs to smokers with

no commensurate benefit.⁴⁷ While this view is hotly contested, it is not relevant in the case of flavored e-cigarette products.



“The consumer’s surplus is the most crucial concept in the measurement of social benefits in any social cost-benefit calculation,” wrote the welfare economist E.J. Mishan.



Consumer surplus analysis is not new to FDA although it has been limited due to a backlash from anti-smoking campaigners.

In August 2011, the FDA issued analysis measuring lost consumer surplus associated with graphic health warnings on cigarette packages. The FDA concluded that lost consumer surplus offset 76%–93% of the predicted health benefits.⁴⁸ The FDA has also estimated the impact of mandatory calorie counts, finding they would cost between \$2.2 billion and \$5.27 billion over 20 years in lost consumer surplus due to foregone consumption of energy-dense food.⁴⁹

Unlike combustible cigarettes, e-cigarettes are harm reduction products. The success of these products lies in their ability to give consumers utility that other products, such as nicotine replacement therapies, cannot. This is one of the many reasons why e-cigarettes are now the most popular smoking cessation aid in the U.S.⁵⁰

⁴⁷ Lemieux, Pierre. “The war on consumer surplus.” Regulation, Cato Institute. Spring, 2017. <https://object.cato.org/sites/cato.org/files/serials/files/regulation/2017/3/regulation-v40n1-4.pdf>

⁴⁸ Norton, Edward, Jeffrey A. Smith and Helen Levy. “Improving Cost-Benefit Analysis of Tobacco Regulation.” August 2011. <https://www.psc.isr.umich.edu/research/project-detail/35956>

⁴⁹ “Food Labeling: Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments Final Regulatory Impact Analysis.” Office of Regulations, Policy, and Social Sciences Center for Food Safety and Applied Nutrition. November, 2014. <https://www.fda.gov/downloads/Food/IngredientsPackagingLabeling/LabelingNutrition/UCM423985.pdf>

⁵⁰ Rodu, Brad and Nantaporn Plurphanswat. “Quit Methods Used by American Smokers, 2013–2014.” International Journal of Environmental Research and Public Health. October 4, 2017. <http://www.mdpi.com/1660-4601/14/11/1403/htm>

Recognizing the utility or enjoyment consumers derive from e-cigarettes is crucial in evaluating their value as harm reduction products. If all utility besides nicotine delivery is removed from these products, there will be less incentive for smokers to switch. As of yet, no one has argued, as they have in the case of combustible cigarettes, that consumer surplus should be ignored when analyzing the value of the e-cigarettes.

There is no justification for supplanting the preferences of e-cigarette consumers for the preferences of those engaged in research or advocacy demanding stricter e-cigarette regulation when assessing the desirability of a tobacco product standard for e-cigarette flavors.

Consumers must be adequately informed of both the risks and rewards of e-cigarettes. But forbidding the option to consume certain kinds of e-cigarette flavors will clearly diminish consumer surplus for many if not most current e-cigarette users, which poses an existential threat to their success in reducing tobacco-related harms, and would doubtless fail a credible cost-benefit analysis.

PART 7

MARKETING

The FDA has raised concerns over the marketing of e-cigarettes with so-called “kid-appealing” flavors.⁵¹ Common flavors cited include bubblegum, cotton candy, and creme brulee. But as has already been discussed, fruit, dessert, and pastry flavors are extremely popular with current adult e-cigarette users.

The categorization of these flavors as “kid-friendly” is not just fundamentally subjective but directly contradictory to the patterns of use among adult e-cigarette users. In 2017, marijuana and alcohol were far more prevalent among youth than e-cigarettes.⁵² Yet there is no suggestion that the flavor of marijuana, beer or wine is designed to appeal to children or is the primary cause of youth use of these products. Youth use of adult products is determined by a number of factors such as curiosity, peer influence, and home environment.

Marketing of e-cigarette products is routinely demonized as one of the causes of youth use of these products. Yet there is little empirical evidence to suggest this is the case beyond associations of youth e-cigarette users recalling seeing e-cigarette marketing. The problem

⁵¹ Gottlieb, Scott. “Remarks by Commissioner of Food and Drug Administration— Protecting American Families: Comprehensive Approach to Nicotine and Tobacco” U.S. Food and Drug Administration, July 28, 2017. <https://www.fda.gov/NewsEvents/ Speeches/ucm569024.htm>

⁵² Johnston, Lloyd D et al. “Monitoring the Future Survey: National Survey Results on Drug Use.” The National Institute on Drug Abuse National Institutes of Health. January, 2018. http://www.monitoringthefuture.org/pubs/monographs/mtf-overview2017.pdf?mod=article_inline

with such associations is that they only measure what an individual recalls, not how much they actually saw, and there is no establishment of a causal relationship.

It is true that young people are more susceptible to advertising, but it has also been recognized that by the age of 11 children quickly distinguish between regular programming and advertising and have “acquired the general capability to recognize commercial persuasion.”⁵³ It is certainly a laudable ambition that no advertising of adult products should appeal to children, but when the age of purchase for e-cigarette is 18 or 21, it is nearly impossible for marketers to produce material that appeals to a 21-year-old that won’t appeal to some 16-year-olds.

Marketing is vitally important for promoting e-cigarette use among adult smokers. Marketing imparts information to consumers and alerts them to the existence of new flavors and products, which may facilitate their switch from smoking to e-cigarettes. Because some children may be exposed to e-cigarette marketing is no case for draconian restrictions. Minors are forbidden from purchasing alcohol but frequently encounter alcohol advertising online, on television and on the radio. No one would suggest that alcohol advertising should be severely restricted because a minority of teens who illicitly obtain alcohol have been exposed to alcohol marketing.



E-cigarette manufacturers are already severely impeded from informing consumers about the benefits of their products.



E-cigarette manufacturers are already severely impeded from informing consumers about the benefits of their products. Due to the Modified Risk Tobacco Application process, e-cigarette manufacturers have to negotiate an expensive and complex regulatory hurdle just to communicate accurate and truthful information to their consumers, such as that e-cigarettes are substantially less dangerous than cigarettes. Not only is this damaging the potential of e-cigarette products to reduce tobacco-related harms but it may very well be

⁵³ Robertson, Thomas and John R. Rossiter. “Children’s Attributions of Intent in Television Commercials.” *Advances in Consumer Research* Volume 1. 1974.
<http://www.acrwebsite.org/volumes/5658/volumes/v01/NA-01>

unconstitutional. According to Jonathan H. Adler, professor of law at Case Western University School of Law: “Insofar as the federal Tobacco Act, and the FDA’s implementing regulation, prohibit product makers and sellers from making factually true statements about their products, they likely violate the First Amendment.”⁵⁴

The deleterious effects of e-cigarette advertising restrictions were documented in a 2018 study published in the National Bureau of Economic Research. The study was the first of its kind to provide causal evidence on whether e-cigarette advertising on television and in magazines encourages adult smokers to quit.

The authors concluded the answer was yes for TV advertising but no for magazine advertising. The results indicated that a policy banning TV advertising of e-cigarettes would have reduced the number of cigarette smokers who quit in the recent past by approximately 3%, resulting in roughly 105,000 fewer quitters. The authors added that if FDA were not “considering regulations and mandates that would likely eliminate many e-cigarette producers during our sample period, e-cigarette ads might have reached the number of nicotine replacement therapy TV ads during that period. That would have increased the number of smokers who quit by around 10%, resulting in an additional 350,000 quitters.”⁵⁵

Accurate advertising and marketing are also critical in correcting the widespread misperception around the relative risks of e-cigarette products. At present, consumers are grossly misinformed about the risks of e-cigarettes, which prevents switching and results in a suboptimal satisfaction of preferences.⁵⁶

⁵⁴ Adler, Jonathan H. “Why FDA regulations limiting e-cigarette marketing may cost lives and violate the Constitution.” Reason.com. December 12, 2017. <https://reason.com/volokh/2017/12/12/why-fda-regulations-limiting-e>

⁵⁵ Dhaval, M et al. “Does E-Cigarette Advertising Encourage Adult Smokers to Quit?” National Bureau of Economic Research. February, 2018. <http://www.nber.org/papers/w24277>

⁵⁶ Viscusi, Kip W. “Risk Beliefs and Preferences for E-cigarettes.” American Society of Health Economists and Massachusetts Institute of Technology. April 20, 2016. https://www.mitpressjournals.org/doi/10.1162/AJHE_a_00042

PART 8

THE PRECAUTIONARY PRINCIPLE

There is a lack of evidence about the appeal of e-cigarette flavors to youth, and how widespread or frequent such use actually is. Still, many public health groups are urging FDA to counter in advance any possible harms that may arise, such as nicotine addiction, by developing an onerous product standard that would in effect prohibit the vast majority of the 7,000 non-tobacco e-cigarette flavors on the market.

This is an application of the precautionary principle. There are many definitions of the precautionary principle, most of which are vague, but the following definition from the Wingspread Statement, a consensus document drafted and adopted by environmental activists and academics in January 1998, applies aptly to the case for restricting e-cigarette flavors: “When an activity raises threats of harm to human health or the environment, precautionary measures should be taken even if some cause and effect relationships are not fully established scientifically. In this context the proponent of an activity, rather than the public, should bear the burden of proof.”⁵⁷

Cause and effect relationships, both in terms of e-cigarette use and subsequent cigarette smoking and appeal of e-cigarette flavors to youth, have clearly not been fully established

⁵⁷ “Wingspread Statement on the Precautionary Principle.” Science and Environmental Health Network, <http://www.sehn.org/wing.html>.

scientifically. Harvard law professor and former administrator of the Office of Information and Regulatory Affairs in the Obama administration, Cass Sunstein highlights some of the major flaws of a precautionary approach in regulatory policy: “The precautionary principle, for all its rhetorical appeal, is deeply incoherent. It is of course true that we should take precautions against some speculative dangers. But there are always risks on both sides of a decision; inaction can bring danger, but so can action. Precautions, in other words, themselves create risks—and hence the principle bans what it simultaneously requires.”⁵⁸



Banning or restricting e-cigarette flavors, when no scientific basis has been established to do so, creates the risk that current e-cigarette users may revert to smoking or that smokers who may have switched to e-cigarettes continue to smoke.



Banning or restricting e-cigarette flavors, when no scientific basis has been established to do so, creates the risk that current e-cigarette users may revert to smoking or that smokers who may have switched to e-cigarettes continue to smoke. The FDA must be cognizant not just of the risks of inaction with regards to e-cigarette flavors but the risks of action. Remarkably, many advocates of precaution in e-cigarette regulation never apply the precautionary principle to the risk of action. Instead, they seek to further burden the e-cigarette market, which already faces substantial regulatory costs under FDA’s Deeming Rule. As University of Texas law professor Frank Cross observes: “The truly fatal flaw of the precautionary principle, ignored by almost all the commentators, is the unsupported presumption that an action aimed at public health protection cannot possibly have negative effects on public health.”⁵⁹

The dangers of precaution are already prominent in FDA’s own history of drug approvals. The delays in drug approvals caused by FDA’s demand for drugs to be demonstrated as

⁵⁸ Sunstein, Cass R. “Throwing Precaution to the Wind: Why the ‘Safe’ Choice Can Be Dangerous.” Boston Globe. July 13, 2008. http://archive.boston.com/bostonglobe/ideas/articles/2008/07/13/throwing_precaution_to_the_wind/

⁵⁹ Cross, Frank B. “Paradoxical Perils of the Precautionary Principle.” Washington and Lee Law Review 53, no. 3. 1996. <https://scholarlycommons.law.wlu.edu/cgi/viewcontent.cgi?article=1656&context=wlulr>

“safe and effective” pose major risks to public health, despite their seemingly innocuous nature. If a new medical treatment will save lives almost immediately once approved, then it is necessarily the case that the longer the approval process, the more people will die awaiting treatment.⁶⁰

Jonathan H. Adler points to the example of Misoprostol, which prevents gastric ulcers and was first approved in some nations in 1985. Misoprostol, however, was not approved in the U.S. until 1988 and was subjected to a nine-and-a-half-month review process. Had Misoprostol been approved more quickly, Adler estimates it could have saved between 8,000 to 15,000 lives. By attempting to ensure absolute safety and efficacy, FDA created risk by preventing the use of Misoprostol by patients suffering from gastric ulcers.⁶¹

According to modeling by Levy et al. replacement of cigarettes by e-cigarettes over a 10-year period yields 6.6 million fewer premature deaths with 86.7million fewer life years lost under their optimistic scenario. Under the model’s pessimistic scenario, 1.6 million premature deaths are averted with 20.8 million fewer life years lost.⁶²



E-cigarettes present an enormous opportunity for tobacco harm reduction.



E-cigarettes present an enormous opportunity for tobacco harm reduction. Limiting their appeal or degrading their characteristics through prohibiting or requiring specific demonstration of individual flavors’ efficacy in aiding smoking cessation presents far greater risks than the disastrous experience of Misoprostol.

⁶⁰ Kazman, Sam. “Deadly Overcaution: FDA’s Drug Approval Process.” *Journal of Regulation and Social Costs*. September, 1990. <https://cei.org/content/deadly-overcaution-fdas-drug-approval-process>

⁶¹ Adler, Jonathan H. “The Problems with Precaution: A Principal without Principle.” American Enterprise Institute. May 25, 2011. <http://www.aei.org/publication/the-problems-with-precaution-a-principle-without-principle/>

⁶² Levy et al. “Potential deaths averted in USA by replacing cigarettes with e-cigarettes.” *Tobacco Control*. October 2, 2017. <https://tobaccocontrol.bmj.com/content/tobaccocontrol/early/2017/08/30/tobaccocontrol-2017-053759.full.pdf>

The UK Royal College of Physicians (RCP) recognized the dangers of employing the precautionary principle with regards to e-cigarette regulation in its 2016 report “Nicotine without smoke: Tobacco Harm Reduction.” The RCP argues that if regulations make e-cigarettes “less easily accessible, less palatable or acceptable, more expensive, less consumer friendly or pharmacologically less effective, or inhibits innovation and development of new and improved products, then it causes harm by perpetuating smoking.” Heavily restricting or prohibiting non-tobacco e-cigarette flavors would impose massive real-world costs in the hopes of achieving purely hypothetical benefits.

8.1

FLAVOR BANS WILL BENEFIT TOBACCO COMPANIES

Following Scott Gottlieb’s September 12th announcement that FDA may withdraw non-tobacco e-cigarette flavors from the market to combat youth vaping, stocks in major tobacco companies surged.⁶³ At first glance, this may appear surprising as tobacco companies such as Altria manufacture also manufacture non-tobacco e-cigarette flavors. However, the market share tobacco companies control of closed e-cigarette products is well below that of their chief rival Juul. Between July 2017 and July 2018, Juul sales skyrocketed by 800% and account for around 75% of that part of the closed system e-cigarette market that is tracked by Nielsen. Flavors have been a critical part of Juul’s success along with an easy-to-use device and high nicotine content, all of which ease the transition from smoking to vaping. If there is one company that is set to lose through flavor prohibition, it is Juul, and if there is one of set of companies set to gain it is traditional tobacco companies.

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⁶³ Bentley, Guy. “The FDA’s assault on vaping is a gift to Big Tobacco.” *Washington Examiner*. September 13, 2018. <https://www.washingtonexaminer.com/opinion/the-fdas-assault-on-vaping-is-a-gift-to-big-tobacco>

As well as manufacturing traditional cigarettes, tobacco companies such as Reynolds American and Altria are hoping to sell other safer products such as heat-not-burn tobacco products, which are not yet available in the U.S. market. While the addition of these products would be a welcome step forward for tobacco harm reduction, providing yet another option for smokers to switch, exclusive e-cigarette companies such as Juul, which sell no tobacco, are put at a competitive disadvantage relative to tobacco companies if their portfolio of flavors is severely restricted.

This was made clear by the reaction of financial analysts to Gottlieb's September 12th announcement. "Given that big tobacco has yet to find a productive way to meaningfully compete against Juul, an FDA decision to pull flavors from the market would be a notable positive for MO (Altria), BATS (British American Tobacco), IMB (Imperial Brands), and JT (Japan Tobacco) as it would reset the competitive landscape in vapor," said Cowen Equity Research.

This dynamic was further highlighted by Altria's decision on October 25th to remove its line of pod-based vapor products until FDA approves such products, and withdraw all of its non-tobacco and non-menthol e-cigarette flavors. Altria did, however, leave its cartridge-based products on the market, which is hardly surprising as these account for the majority of its e-cigarette product sales. Reacting to Altria's decision, Wells Fargo analyst Bonnie Herzog wrote: "Politically, we believe this was the right decision since it shows with action, and not just with words, that MO is willing to work with the FDA." On October 31st, FDA gave more detail as to its plans to combat youth e-cigarette use, which could include bans and restrictions on non-tobacco e-cigarette flavors. Reacting to the announcement, Herzog wrote: "Bottom line—We continue to see MO & Reynolds/BAT as much better positioned especially relative to Juul in any potential FDA action."

It is clear that traditional tobacco companies are finding it exceedingly difficult to compete with Juul. As so often happens when companies cannot meaningfully compete, they support regulations that will actively harm their competitors. A flavor ban would be a laser-guided missile pointed squarely at a company and set of companies that do not produce tobacco cigarettes and would unintentionally leave tobacco companies in a better position relative to exclusive e-cigarette companies. The FDA continues to insist it wants to "keep this option (e-cigarettes) for adults open." But instead of keeping this option open, FDA is contemplating removing the vast majority of e-cigarette options open to adults. The more e-cigarette options that are available to adult smokers, the worse it is for traditional cigarette companies and the better it is for those wanting to quit tobacco.

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The FDA is rightly concerned with youth use of e-cigarettes, including flavored e-cigarettes. Gottlieb has signaled there will be stricter enforcement of age of purchase laws at convenience stores, where the vast majority of illegal e-cigarette sales take place. But in a rush to find a solution to the problem of youth use, FDA may be unintentionally giving a helping hand to the makers of traditional cigarettes whose main competitor is succeeding, thanks in part to the portfolio of flavors it offers to adult smokers trying to kick their habit. Any policy that harms the exclusive makers of reduced-risk products such as e-cigarettes more than the makers of traditional cigarettes is not in the interests of public health.

CONCLUSION

The available evidence on flavored e-cigarettes suggests that flavors in and of themselves are not especially appealing to non-smoking adults or adolescents. There is, however, a substantial and growing literature on how and why these products appeal to smoking adults and their potential to help consumers switch from smoking to less-harmful vaping.

A tobacco product standard that prohibits the vast majority of e-cigarette flavors will not just degrade the value proposition of these products, it will stifle further innovation in the market for reduced-risk nicotine products. Until more substantial and credible evidence emerges clearly demonstrating that these products produce a net public health harm, FDA should refrain from acting against flavored e-cigarettes.

ABOUT THE AUTHOR

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