
Majority Staff Report | Permanent Subcommittee on Investigations | United States Senate

The Youth Vaping Epidemic:

Federal Regulation of E-cigarettes and the Rise of JUUL and Puff Bar

Chairman Richard Blumenthal

Note From The Chair

This is a story of failure: Failure of regulators to implement, enforce, and publicize the dangers of vaping to America's youth. Failure to prevent predatory actors from capitalizing on regulatory loopholes. Failure by the federal agency charged with safeguarding public health and protecting Americans from harm to satisfy its mandate. Failure to preserve decades of progress in combatting youth use of tobacco products.

This report details the ways in which the Food and Drug Administration ("FDA") became complicit in enabling the tobacco industry to grab victory from the jaws of defeat. It tells the story of how a series of opportunistic upstarts were able to take advantage of and profit from these failures in plain sight. In one case, an e-cigarette company built its success by following the playbook that traditional tobacco companies employed years prior: emphasizing flavors that appealed to youth and young adults; adopting a colorful, youthful, and "cool" marketing campaign; and advancing "youth prevention" efforts that may have actually served to promote nicotine products to youth and young adults. In another, two inexperienced entrepreneurs were able to capitalize on the success of the former and flood the market with yet another new product and a variety of flavors that quickly became the most popular brand among youth. In revealing certain never-before-heard details of these companies' strategies, this report illustrates how the FDA's iterative approach to regulating the e-cigarette industry and addressing the youth vaping crisis has failed.

Because of these failures, youth use of e-cigarettes remains nearly three times higher than a decade ago. While there has been some recent progress in combatting the youth vaping epidemic, it is not nearly enough. Much more must be done, and quickly, to ensure that even more youth do not become hooked on an addictive substance that could impact the rest of their lives.

It is imperative that we do not lose yet another new generation of addicts to the alluring temptation of nicotine. We must continue to be vigilant and not assume that past successes will protect our youth from future failures. Accordingly, this report includes 10



recommendations to enhance FDA's enforcement capabilities, increase public awareness, and institute other reforms to protect our nation's youth from further harm.

Finally, I want to thank Senator Tom Carper and former Senator Rob Portman for starting this investigation during the 116th Congress and for the work they and their staff contributed to this report, as well as Ranking Member Ron Johnson for supporting this investigation.



Chairman Richard Blumenthal
U.S. Senate Permanent Subcommittee on Investigations



TABLE OF CONTENTS

EXECUTIVE SUMMARY	1
PART I: BACKGROUND	7
I. TOBACCO INDUSTRY TECHNIQUES TO APPEAL TO YOUTH AND YOUNG ADULTS.....	8
II. TOBACCO MASTER SETTLEMENT AGREEMENT AND DECLINING YOUTH SMOKING RATES	10
III. THE RISE OF E-CIGARETTES	11
IV. THE YOUTH E-CIGARETTE EPIDEMIC	13
PART II: THE FEDERAL GOVERNMENT CHOSE NOT TO ACT AGAINST FLAVORED E-CIGARETTES IN 2016, CONTRIBUTING TO THE CONTINUING YOUTH VAPING EPIDEMIC.....	20
I. THE FOOD AND DRUG ADMINISTRATION REGULATES TOBACCO PRODUCTS.....	20
A. FDA Began Efforts to Regulate E-cigarettes After a 2009 Legal Challenge..	21
B. FDA Published the Final Deeming Rule in May 2016	23
II. OTHER FEDERAL AGENCIES PROVIDED INPUT ON THE TOBACCO DEEMING RULE.....	23
A. Office of Information and Regulatory Affairs within the Office of Management and Budget.....	24
B. Small Business Administration Office of Advocacy	25
C. Domestic Policy Council.....	26
III. THE FEDERAL GOVERNMENT MISSED AN OPPORTUNITY TO CURB YOUTH E-CIGARETTE USE WHEN IT CHOSE NOT TO ADDRESS FLAVORED E-CIGARETTE PRODUCTS IN THE FINAL DEEMING RULE	27
A. FDA Sought to Address Flavored Products and Youth Usage, Among Other Issues.....	27
B. FDA’s Proposed Deeming Rule Prompted Concerns from Industry and Federal Agencies	31
C. FDA Officials Believed the Proposed Flavor Language Would Be Included in the Final Deeming Rule.....	34
D. In Early 2016, HHS Reconsidered the Flavor Language Due to Potential Economic Consequences for Small Businesses	35

E.	The Federal Government Struck the Flavor Language in the Final Deeming Rule.....	38
IV.	YOUTH E-CIGARETTE USAGE GREW DRAMATICALLY AFTER THE PUBLICATION OF THE FINAL DEEMING RULE.....	41
PART III:	JUUL CAPTURED THE E-CIGARETTE MARKET AFTER 2016, USING FLAVORED PRODUCTS AND OTHER TECHNIQUES THAT APPEALED TO YOUTH AND YOUNG ADULTS.....	43
I.	COMPANY BACKGROUND	43
II.	JUUL MARKETED AND PROFITED FROM A PORTFOLIO OF NON-TRADITIONAL FLAVORS.....	45
A.	Non-Traditional Flavored Pods Were Central to JUUL’s Rise in the E-cigarette Market	46
B.	JUUL Viewed Flavors as Important Because They Encouraged Customer Use and Cemented Loyalty	49
C.	JUUL Focused on Non-Traditional Flavors Despite Knowing They Appealed to Youth and Young Adults.....	51
III.	JUUL USED OTHER MARKETING TECHNIQUES THAT ATTRACTED YOUTH	54
A.	The Vaporized Launch Campaign.....	55
B.	Social Media.....	64
IV.	JUUL KNEW IT APPEALED TO YOUTH BUT FAILED TO PREVENT YOUTH PURCHASES OF ITS PRODUCTS	68
A.	Only After Receiving Negative Feedback about the Youthfulness of the Vaporized Campaign, JUUL Rebranded and Attempted to Remove Traces of Vaporized Imagery	69
B.	JUUL Knew Social Media Activity Contributed to Its Popularity Among Underage Users but Struggled to Curb Youth-Related Social Media Activity Related to Its Products	76
C.	JUUL Knew Youth Subverted the Website’s Age Verification Controls but Failed to Sufficiently Strengthen Those Controls	81
D.	JUUL Did Not Undertake Robust Efforts to Understand or Prevent Social Sourcing.....	84
V.	JUUL’S YOUTH PREVENTION EFFORTS MIRRORED TOBACCO INDUSTRY TECHNIQUES AND MAY HAVE MISLED SCHOOLS.....	85
A.	JUUL’s Youth Prevention Efforts	85
B.	JUUL Failed to Research Prior Tobacco Industry Outreach Before Launching Its Youth Prevention Efforts.....	89

C.	Comparisons to the Tobacco Industry’s Youth Outreach Led JUUL to Discontinue Its Youth Prevention Program	91
D.	JUUL Representatives Oversold the Feasibility of Anti-Vaping Technology	93
	PART IV: THE FEDERAL GOVERNMENT CONTINUED TO CHANGE E-CIGARETTE REGULATORY ENFORCEMENT DESPITE JUUL’S RISE AND THE YOUTH VAPING EPIDEMIC	97
I.	IN 2017, FDA EXTENDED COMPLIANCE DEADLINES FOR PRE-MARKET AUTHORIZATION, ALLOWING FLAVORED E-CIGARETTES TO STAY ON THE MARKET WITH MINIMAL OVERSIGHT	98
II.	FDA MOVED UP THE COMPLIANCE DEADLINE AFTER BEING SUED FOR DELAYING E-CIGARETTE ENFORCEMENT AND RECEIVING ADDITIONAL DATA ON YOUTH E-CIGARETTE USE	99
III.	THE MARCH 2019 DRAFT GUIDANCE DID NOT COVER MINT AND MENTHOL FLAVORED E-CIGARETTES, ALLOWING COMPANIES TO CONTINUE MARKETING THESE PRODUCTS	101
IV.	ALTHOUGH THE FEDERAL GOVERNMENT SIGNALLED IT WOULD BAN FLAVORED E-CIGARETTES, IT REVERSED COURSE	103
V.	FDA’S MOST RECENT GUIDANCE ANNOUNCED ENFORCEMENT PRIORITIES FOR SOME, BUT NOT ALL, FLAVORED E-CIGARETTE PRODUCTS	104
	PART V: PUFF BAR SWIFTLY BECAME THE MOST POPULAR E-CIGARETTE BRAND AMONG YOUTH AFTER JUUL WAS LARGELY SIDELINED.....	107
I.	PUFF BAR’S RAPID RISE IN YOUTH POPULARITY FILLED A VOID IN THE MARKET LEFT BY JUUL’S REMOVAL OF FLAVORS.....	107
A.	Puff Bar Products and Popularity in 2019-2020.....	108
B.	Puff Bar Products and Popularity in 2021-2022	111
II.	PUFF BAR’S EARLY ORIGINS ARE MURKY, BUT TWO INEXPERIENCED CEOS WERE ABLE TO ACQUIRE THE BRAND AND CONTINUE ITS SUCCESS	113
A.	The Early Origins of Puff Bar and Cool Clouds.....	113
B.	Mr. Minas and Mr. Beltran Contributed to Puff Bar’s Success Before Becoming Co-CEOs of the Company	114
C.	Mr. Minas and Mr. Beltran Acquired and Sought to Continue Puff Bar Despite Public Scrutiny	116
III.	PUFF BAR LEARNED FROM JUUL’S SUCCESSES AND INTENTIONALLY ADOPTED SOME OF JUUL’S PRACTICES AND AVOIDED SOME OF ITS MISTAKES.....	117
A.	Puff Bar Benefited from JUUL’s Downfall and Ultimately Developed a Similar Reputation for Its Youth Appeal	117

B. Similar to JUUL, Puff Bar Marketed and Profited from a Portfolio of Non-Traditional Flavors	118
C. Puff Bar Was Influenced by JUUL’s “Simple” Branding.....	124
D. Puff Bar Adopted JUUL’s Five Percent Nicotine Concentration	125
E. Although Puff Bar Learned from JUUL’s Mistakes and Avoided Certain Marketing Efforts, the Company Knew That Its Success Was Based on Brand Notoriety and User-Generated Content	126
IV. PUFF BAR KNEW ITS PRODUCTS APPEALED TO YOUTH BUT FAILED TO PREVENT YOUTH PURCHASES AND YOUTH APPEAL OF ITS PRODUCTS.....	133
A. Puff Bar Was Aware of the Rise of Youth Vaping and Knew It Was Popular Among Youth	133
B. Puff Bar’s Co-CEOs Were Aware Youth and Young Adults Could Easily Purchase Company Products at Retail Stores	136
C. Puff Bar Discontinued Some Flavors That Would Appeal to Youth and Changed Flavor Names, but Its Products Continued to Resonate with Youth.....	137
D. Puff Bar’s Social Media Account Was Age Restricted, but the Account Reached Users Under the Age of 21.....	138
E. Puff Bar Took Other Actions to Prevent Youth and Young Adults from Obtaining Its Products, but These Efforts Were Limited.....	139
V. PUFF BAR’S QUICK RISE LED TO A QUICK DOWNFALL, BUT MANAGED TO BECOME THE MOST POPULAR BRAND AMONG YOUTH ALONG THE WAY	141
PART VI: RECENT FDA ACTIONS CONTINUE TO FALL SHORT TO COMBAT THE YOUTH VAPING EPIDEMIC AND UNAUTHORIZED E-CIGARETTES.....	143
I. THE 2023 NYTS RESULTS AND FDA’S STRUGGLE TO COMBAT UNAUTHORIZED E-CIGARETTES	144
II. FDA HAS FAILED TO REVIEW E-CIGARETTE PMTAS PROMPTLY	146
III. FDA OBTAINED AUTHORITY OVER NON-TOBACCO NICOTINE PRODUCTS LIKE SYNTHETIC NICOTINE AND HAS YET TO REVIEW ALL RELATED PMTAS	148
IV. FDA ENFORCEMENT ACTIONS RELATED TO E-CIGARETTES.....	148
V. THE REAGAN-UDALL FOUNDATION EVALUATION FOUND TROUBLING ISSUES WITH FDA CTP	151
CONCLUSION	153

EXECUTIVE SUMMARY

The decline in cigarette smoking rates among U.S. youth, one of the great public health successes of the early 21st century, may soon be overshadowed by a new nicotine addiction epidemic spawned by federal regulatory failure. Today, millions of the nation's middle and high school students consume nicotine in a different form: e-cigarettes, or "vaping." Data from the 2018 National Youth Tobacco Survey ("NYTS") showed that more than 3.6 million middle school and high school students used e-cigarettes in 2018—an increase of more than 2.8 million students from 2013. By 2019, this number had reached a peak of 5 million. These rates were so concerning that the U.S. Surgeon General labeled the phenomenon a "public health epidemic."

While youth e-cigarette usage has declined since 2019, more than 2.13 million middle and high school students continue to use e-cigarettes as of 2023. The vast majority use products that come in fruit, candy, or mint flavors, whose appeal to youth has long been known to both tobacco companies and public health authorities. Without further action, the pattern of recent years—in which federal regulatory shortcomings enable a rotating cast of opportunistic nicotine companies to create a new generation of addicts—could easily repeat itself.

The Subcommittee initiated an investigation into the youth vaping epidemic in March 2019. The Subcommittee reviewed over 713,000 pages of documents from e-cigarette manufacturers JUUL Labs, Inc. ("JUUL") and Puff Bar, the Department of Health and Human Services ("HHS"), Food and Drug Administration ("FDA"), and the Small Business Administration Office of Advocacy ("SBA OA"). The Subcommittee also interviewed and received briefings from former government officials at HHS, FDA, and SBA OA, as well as representatives from JUUL, Puff Bar, social media companies, and public health experts and advocates.

The Subcommittee's multi-year investigation found that the federal government missed a key opportunity to curb youth use of e-cigarettes in 2016, and that subsequent efforts have not fully addressed the risks of flavored e-cigarette products and youth usage. Furthermore, the Subcommittee uncovered new evidence detailing the ways in which e-cigarette companies, including JUUL and Puff Bar, have continued to exploit weaknesses in FDA's approach.

Key Findings

- The federal government missed a crucial opportunity to curb youth e-cigarette use in 2016, enabling a new generation of addicts
 - In 2010, the FDA began drafting a regulation "deeming" e-cigarettes, among other products, to be under their regulatory authority. At the time, flavored tobacco products were a top concern, and FDA initially proposed language that would have required flavored tobacco products to be removed from the market unless and until they received FDA

authorization. Senior executive branch officials, however, removed this language during the interagency review process.

- Interviews with federal officials revealed that some perceived a lack of data supporting its public health benefit or believed data showing harm to the vaping/tobacco industry was stronger. Some officials were also concerned that absent a clear public health benefit, the deeming rule could be vulnerable to industry lawsuits. However, federal agencies did not provide any official records documenting these findings to the Subcommittee. One official told the Subcommittee that they believed former HHS Secretary Sylvia Burwell opposed the flavor language and was involved in removing it; however, other key officials were unsure who ultimately removed the proposed language.
- Regulatory efforts have failed to curtail unauthorized e-cigarette products and stop youth usage
 - In 2014, the U.S. e-cigarette market had an estimated value of \$2.5 billion; by 2018, annual sales had reached nearly \$7 billion.
 - Beginning in January 2017, federal officials compounded problems with e-cigarette enforcement through multiple extensions of compliance deadlines, which allowed manufacturers like JUUL to continue selling their products with little oversight.
 - A September 2019 proposal that would have banned all flavored e-cigarettes was never implemented. Instead, FDA's January 2020 revised guidance prioritized enforcement for flavored cartridge-based e-cigarette products and exempted "self-contained, disposable products." When this policy was implemented, flavored disposable e-cigarettes, like those offered by Puff Bar, quickly filled the void. According to industry sales data, over 5,800 unique disposable e-cigarette products are currently being sold in a variety of flavors, up 1,500 percent from 365 products in early 2020.
 - A U.S. District Court ordered FDA to complete its review of applications e-cigarette manufacturers had filed with the agency to market their products by September 2021. FDA is now more than two years beyond the deadline the court imposed, and applications, including those for e-cigarettes with the largest market share, are still under review.
 - The agency has only recently increased utilizing enforcement mechanisms against e-cigarette companies and retailers.

- JUUL depended on flavors the company knew appealed to youth
 - After launching in 2015, JUUL quickly became the dominant e-cigarette manufacturer. Its exponential growth was driven by the popularity of the Mango and Mint flavors, which together accounted for 70 percent of the company’s sales. In 2018, a consultant for JUUL reportedly equated any move to stop selling non-traditional flavored products with JUUL ending all product sales.
 - Traffic to the company website, retail data, internal communications between executives and employees, and studies the company commissioned showed JUUL’s popularity among youth and young adults. A May 2018 survey by a consultant for JUUL showed that individuals aged 13 to 20 preferred fruit flavors and strongly disliked tobacco and menthol flavors.
 - JUUL employees, including those within the company’s Education & Youth Prevention department, recognized the danger of JUUL products resonating with youth and young adults. A consultant for this department lamented in May 2018, “[t]here always has to be a threat or an enemy and JUUL is a perfect target because JUULs are incredibly popular with students.”
- JUUL’s early marketing appealed to youth, and changes made by the company failed to curb youth interest
 - JUUL found success with a “cool” marketing campaign. Its 2015 “Vaporized” ads promoted the company and its products as “colorful, approachable, dynamic, and fun.” A former JUUL employee told the Subcommittee the company failed to consider how it might appeal to youth. Public backlash led to changes in the ads, but JUUL continued to resonate with younger demographics.
 - JUUL’s early social media posts featured flavor images and lifestyle themes like relaxation, freedom, and sex appeal. The company subsequently struggled to address content related to youth use on platforms like Instagram and YouTube, and to some degree, blamed these failures on the social media platforms’ inaction.
 - In early 2018, JUUL launched an effort to educate youth on the dangers of nicotine. But the company did not examine research on similar efforts by tobacco companies, showing how these initiatives could be ineffective or even encourage youth nicotine use.

- Puff Bar capitalized on JUUL’s removal of flavors to become the number one brand among youth by 2021
 - Puff Bar entered the U.S. market in 2019. Studies showed the company quickly gained popularity among youth. Although the company halted U.S. sales in July 2020, purportedly out of an inability to curb youth use, it quickly relaunched in February 2021 under new owners who saw a market opportunity too lucrative to resist.
 - Nick Minas and Patrick Beltran, who remain the co-CEOs of Puff Bar, had little executive experience and had previously handled online retail and email marketing campaigns for Puff Bar before they acquired the company for \$17.5 million in January 2021. By their own admission, they conducted no due diligence and did not view company financial documents before making the purchase.
 - Although the co-CEOs acquired the company with what Mr. Beltran described as “a lot of solutions” to the problem of youth use, during their tenure, Puff Bar became the most popular brand of e-cigarette among middle and high school students. Mr. Minas and Mr. Beltran respectively admitted that non-traditional flavors popular among youth were “critical” and “extremely important” to their business model, while menthol- and tobacco-flavored products accounted for a tiny percentage of the company’s revenue.

- Puff Bar intentionally adopted some of JUUL’s practices while trying to avoid the scrutiny that brought the company down
 - Puff Bar knowingly adopted JUUL’s emphasis on flavors and “simple” branding style. The company removed certain flavors and simplified flavor names offered under previous owners; Mr. Beltran said that Puff Bar was “trying to be like JUUL.” Puff Bar also followed JUUL’s lead by introducing e-cigarettes with a five percent nicotine concentration.
 - The co-CEOs told the Subcommittee that Puff Bar did not have a marketing strategy and instead relied on brand notoriety. Puff Bar became, per Mr. Beltran, the “Kleenex of disposables”: not just a brand, but a noun synonymous with disposable e-cigarettes. Puff Bar also benefited from user-generated content on social media. At one point, Puff Bar-related hashtags had nearly one billion impressions.
 - Puff Bar’s co-CEOs claimed they tried to limit youth access, including an age verification system on its website, but admitted to the Subcommittee that they knew underage users were able to get around them. The co-CEOs received communications from concerned parents about kids easily purchasing its products at retail stores. They were also unable to explain

how 7.2 percent of Instagram users who had viewed Puff Bar's account in a recent three-month period were between the ages of 13 and 17, despite a 21+ age gate on the account.

In light of these findings, the Subcommittee recommends that FDA immediately complete its review of e-cigarette product applications and utilize all its enforcement tools to the fullest extent, including working with other federal agencies to clear the market of illegal e-cigarettes. Congress should support and fund public awareness, education, and prevention campaigns to educate youth about the health risks of e-cigarettes and other tobacco products and ensure that federal health agencies increase efforts to research and develop smoking cessation and nicotine addiction interventions and therapies for youth and young adults.

Recommendations

- (1) FDA should eliminate enforcement discretion for any flavored e-cigarette products that promote youth and young adult tobacco product initiation and long-term use.
- (2) Congress should examine the degree to which economic and other commercial considerations are and should be factored into the development of public health regulations, especially those intended to address child health.
- (3) FDA should extend the marketing restrictions that apply to cigarettes to e-cigarettes and other similar products, including prohibitions on sponsorship of athletic, music, or cultural events.
- (4) Congress should examine and, where necessary, update the laws governing the marketing of age-restricted products such as e-cigarettes to ensure restrictions on marketing to children are effective and account for modern marketing strategies.
- (5) Congress should pass legislation that codifies, supports, and funds public awareness, education, and prevention campaigns to educate youth and young adults, parents, and healthcare providers about the health risks of tobacco products, including e-cigarettes, as well as outreach to medically underserved communities regarding tobacco-use prevention and cessation.
- (6) Federal health agencies should increase efforts to research and develop smoking cessation and nicotine addiction interventions and therapies for children and young adults.
- (7) The Office of Management and Budget and the Office of Information and Regulatory Affairs should institute reforms, including recommendations from the Government Accountability Office and the Administrative

Conference of the United States, to improve the transparency of the regulatory review process. Additional transparency could help ensure public awareness of the scientific evidence underlying changes to draft rules and responsibility for these changes.

- (8)** Congress should examine the degree to which social media companies' age gating capabilities are effective, and social media companies should determine how these capabilities can be strengthened.
- (9)** FDA should quickly fulfill the court-ordered mandate to review all timely-submitted e-cigarette product applications.
- (10)** FDA should utilize all its enforcement tools and work with other federal agencies, such as the Department of Justice and Customs and Border Protection, to clear the market of illegal tobacco products more rapidly and to help prevent youth use of tobacco products.

PART I: BACKGROUND

In 2021, more than 11.5 percent of adults in the United States—an estimated 28.3 million adults—currently smoked cigarettes, the lowest percentage since 1965.¹ The current adult smoking rate has been gradually declining. In 2005, 20.9 percent of U.S. adults currently smoked cigarettes.² The decline in adult cigarette smoking can be attributed to the increase in tobacco product price, cigarette taxes, smoking bans, and changes in social norms.³ In addition to a decrease in cigarette use among adults, the rate of middle and high school students smoking cigarettes has decreased. Specifically, in 2011, 4.3 percent middle school students reported cigarette use in the past 30 days, which decreased to 1.1 percent in 2023.⁴ In 2011, nearly 15.8 percent of high school students reported cigarette use in the past 30 days, which dropped to 1.9 percent in 2023.⁵

In the United States, tobacco use is the leading cause of preventable disease, disability, and death.⁶ Over 480,000 Americans die annually due to cigarette smoking,⁷ and around 1,600 Americans under the age of 18 smoke their first cigarette every day.⁸ This public health crisis has resulted, in part, from the marketing techniques that major tobacco companies deployed for decades to attract youth and young adults.⁹ Although the U.S. youth smoking rate declined after the 1998 Tobacco Master Settlement Agreement (“MSA”), which ended expansive litigation against tobacco companies,¹⁰ the

¹ U.S. CTRS. FOR DISEASE CONTROL & PREVENTION, *Fast Facts and Fact Sheets: Smoking and Cigarettes*, https://www.cdc.gov/tobacco/data_statistics/fact_sheets/fast_facts/index.htm (last visited Jan. 26, 2024); Monica Cornelius et al., *Tobacco Product Use Among Adults - United States, 2021*, 72 MORBIDITY & MORTALITY WKLY. REP. 475, 477-479 (May 5, 2023).

² U.S. CTRS. FOR DISEASE CONTROL & PREVENTION, *Current Cigarette Smoking Among Adults in the United States*, https://www.cdc.gov/tobacco/data_statistics/fact_sheets/adult_data/cig_smoking/index.htm (last visited Jan. 26, 2024).

³ Mike Stobbe, *US adult cigarette smoking rate hits new all-time low*, ASSOCIATED PRESS (Apr. 27, 2023), <https://apnews.com/article/how-many-people-smoke-us-64987fe2b7bf764c64d4594e5b02e6ea>.

⁴ U.S. CTRS. FOR DISEASE CONTROL & PREVENTION, *Trends in Tobacco Use Among Youth*, https://www.cdc.gov/tobacco/data_statistics/fact_sheets/fast_facts/trends-in-tobacco-use-among-youth.html (last visited Jan. 26, 2024); U.S. CTRS. FOR DISEASE CONTROL & PREVENTION, *Youth and Tobacco Use*, https://www.cdc.gov/tobacco/data_statistics/fact_sheets/youth_data/tobacco_use/index.htm (last visited Jan. 26, 2024).

⁵ U.S. CTRS. FOR DISEASE CONTROL & PREVENTION, *Trends in Tobacco Use Among Youth*, *supra* note 4; U.S. CTRS. FOR DISEASE CONTROL & PREVENTION, *Youth and Tobacco Use*, *supra* note 4.

⁶ U.S. CTRS. FOR DISEASE CONTROL & PREVENTION, *Tobacco Use*, <https://www.cdc.gov/chronicdisease/resources/publications/factsheets/tobacco.htm> (last visited Jan. 26, 2024).

⁷ U.S. CTRS. FOR DISEASE CONTROL & PREVENTION, *Current Cigarette Smoking Among Adults*, *supra* note 2.

⁸ U.S. CTRS. FOR DISEASE CONTROL & PREVENTION, *Tobacco Use*, *supra* note 6.

⁹ For purposes of this report, “youth” refers to individuals under the age 18 and “young adults” refers to individuals aged 18 to 20.

¹⁰ Tamara Schlinger, *The MSA - 20 Years Later*, 3 NAT’L ATT’YS GEN. TRAINING & RSCH. INST. J. 4, 2 (2019); *see also infra* Part I, Section II.

recent rise in e-cigarette use has addicted a new generation of youth and young adults to nicotine.

I. TOBACCO INDUSTRY TECHNIQUES TO APPEAL TO YOUTH AND YOUNG ADULTS

According to the U.S. Surgeon General, almost all adults who become daily smokers began using cigarettes before the age of 18—a developmental stage at which individuals are particularly susceptible to outside influences promoting tobacco use.¹¹ Internal documents from major tobacco companies confirm the importance of younger populations to their industry. In a confidential report from 1983, for example, R.J. Reynolds Tobacco Company (“R.J. Reynolds”) stated:

Why, then, are younger adult smokers important to RJR? Younger adults are the only source of replacement smokers. . . . If younger adults turn away from smoking, the Industry must decline, just as a population which does not give birth will eventually dwindle.¹²

The company also conducted extensive research on the factors that lead adolescents to select their first brand of cigarettes; this research, in part, spurred the company to “youthen” its brand by selecting the cartoon Joe Camel as its key advertising image.¹³ In 1988, the year before the introduction of Joe Camel, profits from Camel cigarette sales to teenage smokers were \$6 million.¹⁴ By 1992, teenage smokers accounted for approximately \$476 million in Camel sales.¹⁵

Joe Camel is just one example of typical advertising in an industry that sought to appeal to youthful aspirations through themes of “independence, liberation, attractiveness, adventurousness, sophistication, glamour, athleticism, social acceptability and inclusion, sexual attractiveness, thinness, popularity, rebelliousness, and being ‘cool.’”¹⁶ Belonging, popularity, and acceptance, specifically, have dominated marketing approaches in the tobacco industry. A 1984 Philip Morris report, for example, stated: “[W]e need not try to understand why young people have a herd instinct. From their choices of food, clothes, transportation, entertainment, heroes, friends, hangouts, etc., it is clear that they do.”¹⁷ A company executive also testified in a deposition for a Department of Justice (“DOJ”) lawsuit that “for some [young adult smokers], the fact that Marlboro is a *popular* brand may be a factor in why they choose Marlboro.”¹⁸

¹¹ OFF. SURGEON GEN., U.S. DEP’T HEALTH & HUM. SERVS., PREVENTING TOBACCO USE AMONG YOUTH AND YOUNG ADULTS: A REPORT OF THE SURGEON GENERAL 9, 10 (2012) [hereinafter 2012 SURGEON GEN. REP.].

¹² *Id.* at 518.

¹³ *Id.* at 519.

¹⁴ OFF. SURGEON GEN., U.S. DEP’T HEALTH & HUM. SERVS., REDUCING TOBACCO USE: A REPORT OF THE SURGEON GENERAL 178 (2000).

¹⁵ *Id.* Prior to the introduction of the Joe Camel campaign, less than one percent of teenagers selected Camel cigarettes. Following the company’s use of the cartoon, an estimated 25 to 33 percent of teenagers selected the brand in 1992. *Id.*

¹⁶ 2012 SURGEON GEN. REP., *supra* note 11, at 508.

¹⁷ *Id.* at 520.

¹⁸ *Id.* (emphasis added).

Flavors also played a prominent role in tobacco industry efforts to appeal to youth and young adults. Philip Morris market research from the 1950s, for example, concluded that the company could “win more young nonsmokers with mildness.”¹⁹ This finding led the company to experiment with additives to enhance the flavor of smoke and improve the smoothness of its products, which resulted in the creation of Marlboro Lights in the early 1970s.²⁰ A 1972 internal memorandum from Lorillard Tobacco Company recommended the company “[e]xplore the feasibility of marketing a flavored cigarette with a skew toward female, youth, and Black markets.”²¹ R.J. Reynolds scientists also found that cigarettes for first-time smokers should be “low in irritation and possibly contain added flavors to make it easier for those who never smoked before to acquire the taste for it more quickly.”²² According to internal industry documents, R.J. Reynolds’ Camel cigarette brand became particularly popular among young smokers in the late 1980s and 1990s due to these added flavors.²³ Marketing documents from another tobacco company during the 1970s also discussed developing a “youth cigarette” product with flavors like cola, apple, and “sweet flavor[s],” because it is a “well known fact that teenagers like sweet products.”²⁴ In addition, data from national surveys in 2004 showed that youth and young adult smokers were more likely to try flavored cigarettes than older smokers.²⁵

In the 1970s, industry research revealed that young smokers were also particularly attracted to menthol-flavored products.²⁶ Tobacco companies knew menthol could mask cigarette smoke harshness and create a cooling sensation, and their research indicated that menthol cigarettes appealed to young smokers due to the perception that they were easier to smoke.²⁷ Lorillard internally identified menthol as the “only accepted ‘alien’ flavor” because it “acts as a soothant to the harshness of the tobacco in the bronchial tube.”²⁸ As a result, the industry began adjusting the level of menthol in cigarettes to capitalize on cigarette youth appeal.²⁹ Menthol cigarettes continue to be popular among youth smokers; in fact, 40.4 percent of middle and high school students who currently smoked cigarettes reported use of menthol cigarettes according to 2023 data from the Centers for Disease Control and Prevention (“CDC”).³⁰

¹⁹ *Id.* at 535.

²⁰ *Id.* at 536. In 2005, Marlboro Lights was the bestselling brand in the U.S. market, and it was particularly popular among adolescents. *Id.*

²¹ PortENDS-155951–52.

²² 2012 SURGEON GEN. REP., *supra* note 11, at 536.

²³ *Id.* at 537.

²⁴ *Id.* at 538.

²⁵ *Id.* at 538–39.

²⁶ *Id.* at 537.

²⁷ *Id.*

²⁸ PortENDS-155951.

²⁹ 2012 SURGEON GEN. REP., *supra* note 11, at 537.

³⁰ U.S. CTRS. FOR DISEASE CONTROL & PREVENTION, *Menthol Smoking and Related Health Disparities*, https://www.cdc.gov/tobacco/basic_information/menthol/related-health-disparities.html (last visited Jan. 26, 2024).

In response to growing concerns about cigarette marketing practices and youth appeal, the tobacco industry developed youth prevention programs and activities beginning in the 1980s.³¹ These programs generally included the dissemination of self-help booklets to families, school-based smoking prevention programs, programs to prevent youth access to tobacco, mass media campaigns advocating against youth smoking, and community-based youth programs.³² In addition, several tobacco companies, including R.J. Reynolds, Brown & Williamson, and U.S. Tobacco, launched the “We Card” campaign in 1995 to distribute age calendars and “We Card” signs to retail stores selling tobacco products.³³ In 1998, Philip Morris and Brown & Williamson worked together to promote the “LifeSkills Training” program throughout U.S. schools, which featured a curriculum designed to increase awareness about the health consequences of tobacco use.³⁴ Additional media campaigns included Lorillard’s “Tobacco is Whacko if You’re a Teen” advertisements, which ran from 1999 to 2004 in youth magazines and on television networks like ESPN and MTV.³⁵ In general, however, these programs and activities often ignored the influence of tobacco advertising on youth tobacco use and failed to address issues of tobacco addiction and related illnesses.³⁶

Internal tobacco industry documents and academic studies have revealed that not only were these prevention initiatives ineffective, but they often promoted youth smoking instead of discouraging it.³⁷ As explained by the U.S. Surgeon General, efforts to prevent tobacco use can actually create positive attitudes about the tobacco industry, including among individuals that anti-smoking messages target.³⁸ These favorable impressions can later lead to tobacco use.³⁹ Investments in youth prevention programs also allowed the tobacco industry to observe factors leading to youth smoking, which it then used to inform marketing efforts.⁴⁰ These issues led the U.S. Surgeon General to conclude that the tobacco industry benefitted from its youth smoking prevention programs and activities.⁴¹

II. TOBACCO MASTER SETTLEMENT AGREEMENT AND DECLINING YOUTH SMOKING RATES

Tobacco industry marketing and promotional efforts with enticing flavors, exciting imagery, and engaging packaging all contributed to a high rate of tobacco use among

³¹ 2012 SURGEON GEN. REP., *supra* note 11, at 552.

³² *Id.* at 552–64. In 1984, for example, the Tobacco Institute joined with the National Association of State Boards of Education to spread its “Helping Youth Decide” booklet. *Id.* at 552. In 2007, Philip Morris released a brochure entitled, “Raising Kids Who Don’t Smoke.” *Id.* at 552–53.

³³ *Id.* at 556.

³⁴ *Id.* at 554.

³⁵ *Id.* at 557.

³⁶ *Id.* at 552.

³⁷ *Id.* at 563.

³⁸ *Id.*

³⁹ *Id.*

⁴⁰ *Id.*

⁴¹ *Id.*

youth and young adults.⁴² By 1997, over one-third of high school students reportedly smoked cigarettes.⁴³ In 1998, 46 state attorneys general attempted to combat this rise in tobacco use, especially among youth, by suing and eventually reaching a settlement agreement with the four largest U.S. tobacco companies—Brown & Williamson, Lorillard, Philip Morris, and R.J. Reynolds.⁴⁴ Known as the Tobacco MSA, the settlement required the tobacco companies to compensate states for billions of dollars in healthcare costs associated with tobacco-related illnesses.⁴⁵ Together, the tobacco companies agreed to pay \$206 billion over a period of 25 years.⁴⁶

The MSA also restricted advertising and marketing of cigarettes, prohibiting tobacco companies from using cartoons and other youth-targeting methods of advertising on billboards or public transportation.⁴⁷ These restrictions, among other factors, resulted in a dramatic reduction in youth smoking rates and contributed to a significant shift in societal perceptions about smoking and the tobacco industry generally.⁴⁸ The most recent findings from the National Youth Risk Behavior Survey revealed that the percentage of high school students currently smoking cigarettes dropped from 36.4 percent of students prior to the MSA to 6.0 percent of students in 2019.⁴⁹ The survey also showed a decrease in frequent smoking from 16.7 percent to 1.3 percent of high school students between 1997 and 2019.⁵⁰

III. THE RISE OF E-CIGARETTES

While the rate of youth smoking has declined, youth and young adult use of e-cigarette products has grown in recent years. As shorthand for a variety of electronic nicotine delivery systems, “e-cigarette” refers to a range of devices that generally allow

⁴² See OFF. SURGEON GEN., U.S. DEP’T HEALTH & HUM. SERVS., THE HEALTH CONSEQUENCES OF SMOKING—50 YEARS OF PROGRESS: A REPORT OF THE SURGEON GENERAL 718 (2014) [hereinafter 2014 SURGEON GEN. REP.]. Cigarette smoking among high school students increased from 1991 to 1997, with use reaching a peak just before the MSA in 1997. In 1991, about one quarter of high school students (27.6 percent of males and 27.3 percent of females) smoked cigarettes. In 1997, the prevalence of current cigarette smoking rose to more than one third of high school students (37.7 percent of males and 34.7 percent of females). In 1991, 18.2 percent of young adults (age 18 to 24) reported daily cigarette use. *Id.* at 724.

⁴³ See *id.* at 718–24.

⁴⁴ Master Settlement Agreement (Nov. 23, 1998), <https://www.naag.org/our-work/naag-center-for-tobacco-and-public-health/the-master-settlement-agreement/>; see also NAT’L ASS’N ATT’YS GEN., NAAG Center for Tobacco and Public Health, https://www.naag.org/naag/about_naag/naag-center-for-tobacco-and-public-health.php (last visited Jan. 26, 2024).

⁴⁵ Master Settlement Agreement (Nov. 23, 1998), <https://www.naag.org/our-work/naag-center-for-tobacco-and-public-health/the-master-settlement-agreement/>.

⁴⁶ Steven A. Schroeder, *Tobacco Control in the Wake of the 1998 Master Settlement Agreement*, 350 NEW ENG. J. MED. 293, 294 (2004).

⁴⁷ NAT’L ASS’N ATT’YS GEN., *supra* note 44. The MSA also created the Truth Initiative, a tobacco prevention foundation focused on preventing teen smoking and encouraging current smokers to quit. Schlinger, *supra* note 10, at 3-4.

⁴⁸ Schlinger, *supra* note 10, at 3-4.

⁴⁹ U.S. CTRS. FOR DISEASE CONTROL & PREVENTION, TRENDS IN THE PREVALENCE OF TOBACCO USE NATIONAL YRBS: 1991—2019 (2020).

⁵⁰ See *id.* Frequent smoking is defined as smoking on 20 or more days 30 days prior to the survey. *Id.*

a user to inhale nicotine, flavors, and other additives through an aerosol.⁵¹ These devices typically include a battery, a reservoir for holding a nicotine solution—often called an “e-liquid”—a heating element that aerosolizes this solution into vapor, and a mouthpiece for the user.⁵²

E-cigarettes are generally classified as first-, second-, and third-generation models based on device features.⁵³ First-generation e-cigarettes include devices known as “cigalikes” because of their similarity to conventional cigarettes in shape and color.⁵⁴ Some first-generation products replicate a cigar or pipe, while others are longer or narrower than a conventional cigarette and use a cartridge design to hold the e-liquid.⁵⁵ Second-generation e-cigarette models resemble pens and are larger and more cylindrical than cigalikes.⁵⁶ These e-cigarettes are often described as “tank systems” because of their transparent reservoirs that contain larger amounts of e-liquid than previous devices with cartridges.⁵⁷ Unlike first-generation e-cigarettes, which were typically disposable, second-generation e-cigarettes can be recharged.⁵⁸ Additionally, most cigalike devices are “closed systems,” and the amount of e-liquid, the nicotine level, and flavors cannot be altered by the user, while second-generation devices are “open systems” that allow users to mix their own e-liquids, flavors, and nicotine concentration levels.⁵⁹ Third-generation e-cigarettes include a variety of products and differ greatly from the shape of traditional cigarettes.⁶⁰ Generally, third-generation e-cigarette models come in square or rectangular shapes and are modifiable, which is why these devices are sometimes referred to as “mods.”⁶¹ These devices are also typically referred to as “vaping” products.⁶²

Most recently, a wide range of easily rechargeable e-cigarettes with high-tech designs, often resembling a USB flash drive, have entered the e-cigarette market.⁶³ These reusable e-cigarettes use “pods,” which allow users to replace a nicotine-

⁵¹ OFF. SURGEON GEN., U.S. DEP’T HEALTH & HUM. SERVS., E-CIGARETTE USE AMONG YOUTH AND YOUNG ADULTS: A REPORT OF THE SURGEON GENERAL 3 (2016) [hereinafter 2016 SURGEON GEN. REP.].

⁵² *Id.* at 11.

⁵³ *Id.*; NAT’L ACADS. SCIS., ENG’G, & MED., PUBLIC HEALTH CONSEQUENCES OF E-CIGARETTES 57 (2018) [hereinafter PUBLIC HEALTH CONSEQUENCES].

⁵⁴ PUBLIC HEALTH CONSEQUENCES, *supra* note 53.

⁵⁵ 2016 SURGEON GEN. REP., *supra* note 51, at 11.

⁵⁶ PUBLIC HEALTH CONSEQUENCES, *supra* note 53.

⁵⁷ 2016 SURGEON GEN. REP., *supra* note 51, at 11.

⁵⁸ *Id.*

⁵⁹ TRUTH INITIATIVE, *E-Cigarettes: Facts, Stats and Regulations*, <https://truthinitiative.org/research-resources/emerging-tobacco-products/e-cigarettes-facts-stats-and-regulations> (June 15, 2021) [hereinafter TRUTH INITIATIVE, *E-Cigarettes*].

⁶⁰ 2016 SURGEON GEN. REP., *supra* note 51, at 151.

⁶¹ *Id.*

⁶² PUBLIC HEALTH CONSEQUENCES, *supra* note 53, at 58.

⁶³ *Id.*

⁶³ Jidong Huang et al., *Vaping Versus JUULing: How the Extraordinary Growth and Marketing of JUUL Transformed the US Retail E-cigarette Market*, 28 TOBACCO CONTROL 146 (2018); TRUTH INITIATIVE, *E-Cigarettes*, *supra* note 58.

containing cartridge or refill a tank with a liquid solution.⁶⁴ In addition, disposable e-cigarettes, which cannot be refilled, have recently dominated the e-cigarette market, accounting for 51.8 percent of sales in tradition retail outlets as of December 2022.⁶⁵



Figure 1: E-Cigarette Product Designs⁶⁶

E-cigarettes entered the U.S. market in 2007,⁶⁷ but little data exists on the prevalence of their use at the national level before 2011.⁶⁸ In 2014, the U.S. e-cigarette market was valued at an estimated \$2.5 billion.⁶⁹ One year later, the e-cigarette by JUUL Labs, Inc. (“JUUL”) entered the market and “single-handedly grew the e-cigarette industry.”⁷⁰ By 2018, e-cigarette sales reached over \$6.8 billion, and by mid-2019, JUUL captured over 70 percent of the e-cigarette market share.⁷¹

IV. THE YOUTH E-CIGARETTE EPIDEMIC

As the industry has grown, public health officials have expressed concerns about the youth appeal of e-cigarettes. The e-liquids used in e-cigarettes often come in flavors like mint, candy, and fruit—the kinds of flavors the tobacco industry used to attract youth customers for decades.⁷² The availability of these flavors, as well as widespread advertising featuring celebrities and marketing through social media, has contributed significantly to the popularity of e-cigarettes among youth.⁷³

These developments have threatened to reverse post-MSA progress in reducing nicotine use among youth and young adults. In 2013, the last year that the National

⁶⁴ CAMPAIGN FOR TOBACCO-FREE KIDS, *Electronic Cigarettes: An Overview of Key Issues* (Mar. 20, 2023), <https://www.tobaccofreekids.org/assets/factsheets/0379.pdf>.

⁶⁵ *Id.*

⁶⁶ *Id.*

⁶⁷ *Id.*

⁶⁸ PUBLIC HEALTH CONSEQUENCES, *supra* note 53, at 26.

⁶⁹ 2016 SURGEON GEN. REP., *supra* note 51, at 149.

⁷⁰ Angelica LaVito, *JUUL Revolutionized E-Cigarettes - and Now the Industry's in Jeopardy*, CNBC (Dec. 16, 2019), <https://www.cnbc.com/2019/12/15/juul-revolutionized-e-cigarettes-and-now-the-industrys-in-jeopardy.html>.

⁷¹ TRUTH INITIATIVE, *E-Cigarettes*, *supra* note 58.

⁷² 2016 SURGEON GEN. REP., *supra* note 51, at 11.

⁷³ *Id.* at 10.

Youth Tobacco Survey (“NYTS”) showed more youth using combustible tobacco than e-cigarettes, 780,000 middle and high school students reported current use—within the past 30 days—of e-cigarettes.⁷⁴ By 2018, NYTS data showed that more than 3.6 million middle school and high school students reported current use of e-cigarettes, an increase of more than 1.5 million students from 2017.⁷⁵ In December 2018, the U.S. Surgeon General released an advisory warning concerning the surge in e-cigarette use among youth, labeling it a “public health epidemic.”⁷⁶

According to the data, e-cigarette use among high school students increased from 1.5 percent (220,000 students) in 2011 to 20.8 percent (3.05 million students) in 2018, and use among middle school students increased from 0.6 percent (60,000 students) in 2011 to 4.9 percent (570,000 students) in 2018.⁷⁷ Results from the 2019 NYTS continued to show alarming rates of e-cigarette use among youth: 35 percent of middle school and high school students reported using e-cigarettes at least once.⁷⁸ Notably, 5.3 million students—27.5 percent of high school students (4.1 million students) and 10.5 percent of middle school students (1.2 million students)—reported current use of e-cigarettes in 2019.⁷⁹

The 2020 NYTS showed a decline in current e-cigarette use among high school and middle school students from the 2019 survey and found that 3.6 million U.S. youths still currently used e-cigarettes.⁸⁰ Specifically, 19.6 percent of high school students (3.02 million) and 4.7 percent of middle school students (550,000) reported current e-cigarette use.⁸¹ In 2021, 11.3 percent of high school students (1.72 million) and 2.8 percent (320,000) of middle school students reported current e-cigarette use.⁸²

⁷⁴ René Arrazola et al., *Tobacco Use Among Middle and High School Students — United States, 2011–2014*, 64 MORBIDITY & MORTALITY WKLY. REP. 381, 383 (Apr. 17, 2015).

⁷⁵ Karen Cullen et al., *Notes from the Field: Use of Electronic Cigarettes and Any Tobacco Product Among Middle and High School Students — United States, 2011–2018*, 67 MORBIDITY & MORTALITY WKLY. REP. 1253, 1276 (Nov. 16, 2018). Between 2017 and 2018, current e-cigarette use among high school students increased 78 percent, from 11.7 percent to 20.8 percent (3.05 million students), and current use by middle school students increased 48 percent, from 3.3 percent to 4.9 percent (570,000 students). U.S. FOOD & DRUG ADMIN., RESULTS FROM 2018 NATIONAL YOUTH TOBACCO SURVEY SHOW DRAMATIC INCREASE IN E-CIGARETTE USE AMONG YOUTH OVER PAST YEAR (2018) [hereinafter RESULTS FROM 2018 NATIONAL YOUTH TOBACCO SURVEY].

⁷⁶ OFF. SURGEON GEN., U.S. DEP’T HEALTH & HUMAN SERVS., ADVISORY ON E-CIGARETTE USE AMONG YOUTH (2018).

⁷⁷ Cullen et al., *supra* note 75, at 1276.

⁷⁸ Teresa Wang et al., *Tobacco Product Use and Associated Factors Among Middle and High School Students – United States, 2019*, 68 MORBIDITY & MORTALITY WKLY. REP. 1, 5 (Dec. 6, 2019) [hereinafter *2019 Tobacco Product Use and Associated Factors*].

⁷⁹ *Id.* “Current use” is the use of an e-cigarette on one or more days during the past 30 days. *Id.* at 3.

⁸⁰ Teresa Wang et al., *E-cigarette Use Among Middle and High School Students – United States, 2020*, 69 MORBIDITY & MORTALITY WKLY. REP. 1310, 1310–12 (Sept. 18, 2020) [hereinafter *2020 E-cigarette Use Among Middle and High School Students*].

⁸¹ *Id.*

⁸² Eunice Park-Lee et al., *Notes from the Field: E-Cigarette Use Among Middle and High School Students – National Youth Tobacco Survey, United States, 2021*, 70 MORBIDITY & MORTALITY WKLY. REP. 1387, 1387-89 (Oct. 1, 2021) [hereinafter *2021 E-cigarette Use Among Middle and High School Students*].

Although the 2021 NYTS data showed a decrease in current use among students, the CDC stated that the 2021 NYTS data should not be compared with previous NYTSs due to a methodology change.⁸³ The 2022 NYTS showed more than 2.5 million students—14.1 percent (2.14 million) high school students and 3.3 percent (380,000) of middle school students—reported current e-cigarette use.⁸⁴ The most recent 2023 NYTS showed a decrease in current e-cigarette use, with more than 2.1 million students reporting current use.⁸⁵ The number of high school students reporting current e-cigarette use declined to 10 percent (1.56 million), and the number of middle school students reporting current e-cigarette use increased to 4.6 percent (550,000).⁸⁶

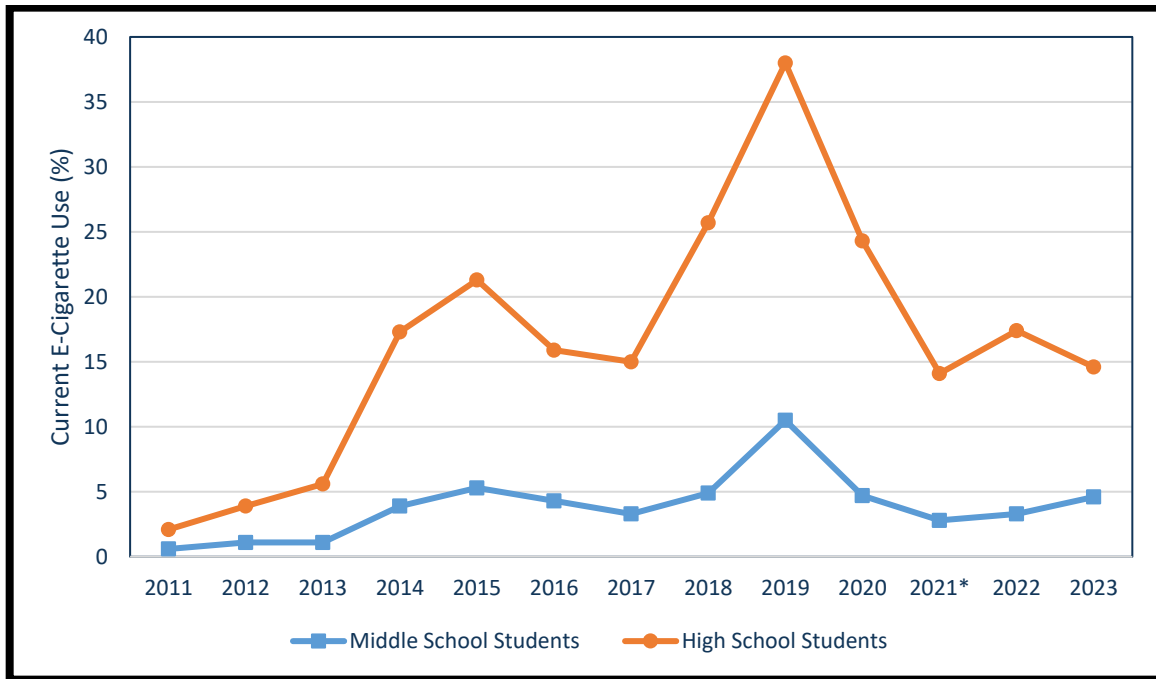


Figure 2: 2011-2023 NYTS Data Showing Current E-Cigarette Use by Middle School and High School Students⁸⁷

⁸³ *Id.* According to the CDC, while previous surveys were primarily conducted on school campuses, the “2021 NYTS was fully conducted amid the global COVID-19 pandemic, during which time eligible students could participate in the survey in classrooms, at home, or at some other place. Differences in tobacco use estimates by location might be due to potential underreporting of tobacco use behaviors or other unmeasured characteristics among youths participating outside of the classroom.” *Id.*

⁸⁴ Maria Cooper et al., *Notes from the Field: E-Cigarette Use Among Middle and High School Students - National Youth Tobacco Survey, United States, 2022*, 71 MORBIDITY & MORTALITY WKLY. REP. 1283, 1283-84 (Oct. 7, 2022) [hereinafter *2022 E-cigarette Use Among Middle and High School Students*].

⁸⁵ Jan Birdsey et al., *Tobacco Product Use Among U.S. Middle and High School Students - National Youth Tobacco Survey, 2023*, 72 MORBIDITY & MORTALITY WKLY. REP. 1173 (Nov. 3, 2023) [hereinafter *2023 Tobacco Product Use Among U.S. Middle and High School Students*].

⁸⁶ *Id.* at 1173, 1175, 1180.

⁸⁷ U.S. FOOD & DRUG ADMIN., *Spotlight on Science - Winter 2021* (Jan. 26, 2021), <https://www.fda.gov/tobacco-products/ctp-newsroom/spotlight-science-winter-2021>; *2021 E-cigarette Use Among Middle and High School Students*, *supra* note 82; *2022 E-cigarette Use Among Middle and High School Students*, *supra* note 84.

The 2020 NYTS showed the dramatic rise in popularity of disposable e-cigarettes among middle and high school students. Among middle and high school current e-cigarette users, disposable e-cigarette use increased nearly 1,000 percent—from 2.4 percent to 26.5 percent among high school students—and approximately 400 percent—from 3 percent to 15.2 percent—among middle school students.⁸⁸ Disposable e-cigarettes were the most commonly used device type reported in 2021 by current student users—55.8 percent among high school students and 43.8 percent among middle school students—as well as in 2022 with 57.2 percent of high school students and 45.8 percent of middle school students reporting disposable e-cigarettes as the types of devices most often used.⁸⁹ The trend continued in 2023, with disposable e-cigarettes being the most commonly used device type by current student users—60.7 percent among all students, including 65.2 percent among high school students and 47.9 percent among middle school students.⁹⁰ Disposable e-cigarettes was followed by prefilled or refillable pods or cartridges, with 16.1 percent of current student users reporting use.⁹¹

The availability of flavored e-cigarette products has also contributed to use by youth and young adults. The 2019 NYTS found that among middle school and high school students who had ever tried e-cigarettes, 22.4 percent cited “flavors, such as mint, candy, fruit or chocolate” as a major motivation for e-cigarette use.⁹² Further, of the 3.6 million students reporting e-cigarette use in 2020, more than eight in 10 reported using flavored products.⁹³ Similarly, in 2021 and 2022, more than 84 percent of current student e-cigarette users overall used flavored e-cigarettes.⁹⁴ In 2023, among all current student e-cigarette users, nearly nine out of 10 current e-cigarette users (89.4 percent) used flavored e-cigarettes with fruit (63.4 percent) being the most popular flavor followed by candy (35 percent), mint (27.8 percent), and menthol (20.1 percent).⁹⁵ A similar trend was observed among current student users of disposable e-cigarettes, with the top reported flavor categories being fruit (70.5 percent), candy (39.8 percent), mint (32 percent), and menthol (18.7 percent).⁹⁶ In addition, for the first time, the 2023 NYTS assessed the use of flavors that included the word “ice” or “iced” in the product name. Among students currently using tobacco products, 57.9 percent of e-cigarette users reported using a flavored e-cigarette with “ice” or “iced” in the flavor name.⁹⁷

⁸⁸ 2020 *E-cigarette Use Among Middle and High School Students*, *supra* note 80.

⁸⁹ 2021 *E-cigarette Use Among Middle and High School Students*, *supra* note 82, at 1388; 2022 *E-cigarette Use Among Middle and High School Students*, *supra* note 84.

⁹⁰ 2023 *Tobacco Product Use Among U.S. Middle and High School Students*, *supra* note 85, at 1180.

⁹¹ *Id.*

⁹² 2019 *Tobacco Product Use and Associated Factors*, *supra* note 78, at 6.

⁹³ 2020 *E-cigarette Use Among Middle and High School Students*, *supra* note 80.

⁹⁴ 2021 *E-cigarette Use Among Middle and High School Students*, *supra* note 82, at 1387; 2022 *E-cigarette Use Among Middle and High School Students*, *supra* note 84, at 1283.

⁹⁵ 2023 *Tobacco Product Use Among U.S. Middle and High School Students*, *supra* note 85, at 1175.

⁹⁶ *Id.*

⁹⁷ *Id.* at 1173, 1175, 1179.

Recent NYTSs have also revealed the most popular e-cigarette brands among high school and middle school students. The 2020 NYTS found that JUUL was the most commonly reported brand by current student e-cigarette users—25.4 percent among high school students and 35.1 percent among middle school students.⁹⁸ In 2021, the NYTS reported that among high school current e-cigarette users, 26.1 percent reported that their usual brand was Puff Bar, followed by Vuse (10.8 percent), SMOK (9.6 percent), JUUL (5.7 percent), and Suorin (2.3 percent).⁹⁹ Middle school current e-cigarette users also reported Puff Bar (30.3 percent) as their usual brand followed by JUUL (12.5 percent).¹⁰⁰ The 2022 NYTS showed that Puff Bar continued to be the most popular brand among students, with 29.7 percent of current student e-cigarette users reporting use of the brand, followed by Vuse (23.6 percent), JUUL (22 percent), SMOK (13.5 percent), and NJOY (8.3 percent).¹⁰¹ The 2023 NYTS reflected the quickly changing e-cigarette market and found many new brands were popular among students. In the most recent NYTS, the most commonly reported brands by current student e-cigarette users were Elf Bar (56.7 percent), Esco Bars (21.6 percent), Vuse (20.7 percent), JUUL (16.5 percent), and Mr. Fog (13.6 percent).¹⁰²

Exposure to traditional and social media marketing tactics also played a significant role in driving e-cigarette use among youth and young adults. The 2019 NYTS, for example, found that 69.3 percent of middle school and high school students reported seeing e-cigarette marketing on a wide range of platforms, such as on the internet, in print media, and at convenience stores.¹⁰³ The 2021 NYTS found that 70.3 percent of all students reported exposure to e-cigarette marketing on the same platforms.¹⁰⁴ In addition, youth and young adults are the largest users of social media, and marketing or user-generated content on these platforms, including Facebook, Instagram, and Twitter, have the ability to shape social norms around behaviors like tobacco use.¹⁰⁵ Research suggests that exposure to e-cigarette content on social

⁹⁸ Teresa Wang et al., *Characteristics of e-Cigarette Use Behaviors Among US Youth, 2020*, 4(6) JAMA NETWORK OPEN e2111336 (June 7, 2021). Response options were: blu, JUUL, Logic, NJOY, SMOK, Suorin, Vuse, “some other brand(s) not listed here” (write-in responses available), and “I don’t know the brand.” *Id.*

⁹⁹ *2021 E-cigarette Use Among Middle and High School Students*, *supra* note 82, at 1388.

¹⁰⁰ *Id.*

¹⁰¹ *2022 E-cigarette Use Among Middle and High School Students*, *supra* note 84.

¹⁰² *2023 Tobacco Product Use Among U.S. Middle and High School Students*, *supra* note 85, at 1180.

¹⁰³ *2019 Tobacco Product Use and Associated Factors*, *supra* note 78, at 7. The CDC assessed exposure to marketing by asking respondents how often they saw advertisements or promotions about e-cigarettes when using the internet, reading newspapers or magazines, going to convenience stores, watching television or streaming services, or going to the movies.

¹⁰⁴ Andrea Gentzke et al., *Tobacco Product Use and Associated Factors Among Middle and High School Students – National Youth Tobacco Survey, United States, 2021*, 71 MORBIDITY & MORTALITY WKLY. REP. 5 (Mar. 11, 2022).

¹⁰⁵ Lauren Czaplicki et al., *Characterising JUUL-Related Posts on Instagram*, 29 TOBACCO CONTROL 612, 612–17 (2020); Pallav Pokhrel et al., *Social Media E-cigarette Exposure and E-Cigarette Expectancies and Use Among Young Adults*, 78 ADDICTED BEHAVS. 51, 51–58 (2018).

media is likely associated with a greater probability of e-cigarette use for youth and young adults.¹⁰⁶

Lack of awareness of the potential health risks associated with e-cigarettes has also played a prominent role in driving e-cigarette use among youth and young adults.¹⁰⁷ A 2018 Truth Initiative study, for example, found that 63 percent of current youth and young adult users of JUUL did not know that the product always contains nicotine.¹⁰⁸ Importantly, the National Academies of Sciences, Engineering, and Medicine (“NASEM”) found that, although some studies indicate e-cigarettes are “likely less harmful” than combustible cigarettes, the long-term health effects and overall safety of e-cigarettes have yet to be determined.¹⁰⁹ The NASEM study concluded, “there is a lack of information regarding the short- and long-term effects of e-cigarettes on the respiratory system” and “exposure of the lungs to various components of the e-cigarette aerosol could potentially damage the respiratory system or worsen preexisting lung disease.”¹¹⁰ The study also determined that, in addition to nicotine, most e-cigarette products contain and release numerous potentially toxic substances, including “fine particulate matter” and metal.¹¹¹

Similarly, while e-cigarette aerosol may contain fewer chemicals and toxins compared to cigarette smoke, researchers from Johns Hopkins University identified a mixture of nearly 2,000 chemicals in four e-cigarette brands, the vast majority of which were unidentified.¹¹² A 2020 Surgeon General’s report noted that “several studies demonstrate e-cigarette aerosol contains fine and ultrafine particles, such that use of the products could potentially increase cardiovascular and respiratory risks.”¹¹³ In 2021, the World Health Organization (“WHO”) Global Tobacco Control Report cited to studies suggesting that e-cigarettes have negative effects on cardiovascular and respiratory health.¹¹⁴

¹⁰⁶ Kristina Jackson et al., *Media Marketing Influences on Adolescents and Young Adult Substance Abuse*, 5 CURRENT ADDICTION REPS. 146, 146–57 (2018); Pokhrel et al., *supra* note 105.

¹⁰⁷ 2016 SURGEON GEN. REP., *supra* note 51, at 88.

¹⁰⁸ TRUTH INITIATIVE, *Action Needed on E-Cigarettes* (Nov. 13, 2020), https://truthinitiative.org/sites/default/files/media/files/2022/03/Truth_E-Cigarette_Factsheet_update_May_2021.pdf.

¹⁰⁹ PUBLIC HEALTH CONSEQUENCES, *supra* note 53, at 221.

¹¹⁰ *Id.* at 406. See also Jeffrey Gotts et al., *What are the Respiratory Effects of E-Cigarettes?*, 366 BMJ 1, 11 (2019) (concluding that “[g]iven the survey data showing increased symptoms of respiratory disease and the many lines of human, animal, and in vitro experimental evidence that e-cigarette aerosol can negatively affect multiple aspects of lung cellular and organ physiology and immune function, e-cigarettes will likely prove to have at least some pulmonary toxicity with chronic and possibly even short term use”).

¹¹¹ *Id.* at 17, 32.

¹¹² Mina Tehrani et al., *Characterizing the Chemical Landscape in Commercial E-Cigarette Liquids and Aerosols by Liquid Chromatography–High-Resolution Mass Spectrometry*, 34, 10 CHEM. RSCH. TOXICOLOGY 2216-2226 (2021).

¹¹³ OFF. SURGEON GEN., U.S. DEP’T HEALTH & HUMAN SERVS., *SMOKING CESSATION: A REPORT OF THE SURGEON GENERAL* 542 (2020).

¹¹⁴ WORLD HEALTH ORG., *WHO REPORT ON THE GLOBAL TOBACCO EPIDEMIC 2021: ADDRESSING NEW AND EMERGING PRODUCTS* 36 (2021).

Additionally, there is limited evidence to suggest that e-cigarettes promote smoking cessation. NASEM found “insufficient evidence” to support a definitive conclusion regarding the use of e-cigarettes as a smoking cessation tool.¹¹⁵ The NASEM study, however, found “substantial evidence” that e-cigarette use increases the risk of youth and young adults using conventional combustible cigarettes.¹¹⁶ The 2020 Surgeon General report on smoking cessation concluded that the “evidence is inadequate to infer that e-cigarettes, in general, increase smoking cessation.”¹¹⁷ The 2021 WHO report found that “evidence on the use of ENDS as a cessation aid is inconclusive.”¹¹⁸ A 2024 updated review by the Cochrane Library’s Tobacco Addiction Group based at the University of Oxford found that e-cigarettes can help smokers stop smoking for at least six months.¹¹⁹ However, the review has been criticized for relying on only seven studies to reach this conclusion.¹²⁰

¹¹⁵ PUBLIC HEALTH CONSEQUENCES, *supra* note 53, at 579. FDA has yet to approve any e-cigarette product as a smoking cessation device. See HASSAN SHEIKH & VICTORIA GREEN, CONG. RSCH. SERV., R45867, U.S. FOOD & DRUG ADMIN. REGULATION OF TOBACCO PRODUCTS 30 (2020); Briefing with U.S. Food & Drug Administration (Mar. 6, 2020).

¹¹⁶ PUBLIC HEALTH CONSEQUENCES, *supra* note 53, at 532–33.

¹¹⁷ The report also concluded that “the evidence is suggestive but not sufficient to infer that the use of e-cigarettes containing nicotine is associated with increased smoking cessation compared with the use of e-cigarettes not containing nicotine, and the evidence is suggestive but not sufficient to infer that more frequent use of e-cigarettes is associated with increased smoking cessation compared with less frequent use of e-cigarettes.” OFF. SURGEON GEN., *supra* note 113, at 11.

¹¹⁸ WORLD HEALTH ORG., *supra* note 114, at 39.

¹¹⁹ Nicola Lindson et al., *Electronic cigarettes for smoking cessation*, 1 COCHRANE DATABASE SYSTEMATIC REVIEWS. CD010216 (2024).

¹²⁰ CAMPAIGN FOR TOBACCO-FREE KIDS, *E-Cigarettes and Cessation* (Jan. 9, 2024), <https://assets.tobaccofreekids.org/factsheets/0414.pdf>.

PART II: THE FEDERAL GOVERNMENT CHOSE NOT TO ACT AGAINST FLAVORED E-CIGARETTES IN 2016, CONTRIBUTING TO THE CONTINUING YOUTH VAPING EPIDEMIC

The U.S. federal government has taken several steps to combat the growing popularity of e-cigarette products among youth and young adults. In 2009, Congress enacted the Family Smoking Prevention and Tobacco Control Act (“TCA”), which amended the Federal Food, Drug, and Cosmetic Act (“FD&C Act”) to enable the Food and Drug Administration (“FDA”) to regulate the manufacture, marketing, sale, and distribution of tobacco products.¹²¹ Congress enacted the TCA, in part, to “protect the public health and to reduce tobacco use by minors.”¹²² Although the TCA covered cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco, it also afforded FDA with broad regulatory authority over any other product the agency “deemed” to meet the definition of a “tobacco product.”¹²³

Soon after the TCA’s enactment, the federal government began developing a rule “deeming” e-cigarettes, among other products, as “tobacco products” within FDA’s authority. Based on input from stakeholders and interested parties, FDA proposed to address nicotine use among youth and young adults by requiring flavored products to be removed from the market within a short timeframe unless and until the products were authorized by FDA. The final rule published in May 2016, however, did not include this provision. White House officials determined that the evidence demonstrating a relationship between flavors and youth vaping did not outweigh the evidence of the negative economic impact the provision would have on the vaping industry. As a result, flavored nicotine products remained on the market, and the federal government missed a key opportunity to combat the youth vaping epidemic. As discussed below, use of JUUL and other e-cigarettes expanded dramatically after 2016 and addicted a new generation of Americans to nicotine. Flavored options, which appeal most strongly to youth and young adult consumers, significantly fueled this expansion. After FDA prioritized enforcement of certain flavors and types of e-cigarettes and JUUL removed its flavors from the market, flavored disposable e-cigarettes, like Puff Bar, exploded onto the market appealing to youth.

I. THE FOOD AND DRUG ADMINISTRATION REGULATES TOBACCO PRODUCTS

The TCA charged FDA with regulating the manufacture, marketing, and distribution of cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless

¹²¹ SHEIKH & GREEN, *supra* note 115, at 2.

¹²² Family Smoking Prevention and Tobacco Control Act, Pub. L. No. 111-31, pmbi., 123 Stat. 1776 (2009).

¹²³ “Tobacco product” is defined as “any product made or derived from tobacco that is intended for human consumption, including any component, part, or accessory of a tobacco product (except for raw materials other than tobacco used in manufacturing a component, part, or accessory of a tobacco product).” It does not include a drug (as defined under section 201(g)(1) of the FD&C Act), a device (as defined under section 201(h) of the FD&C Act), or a combination product (as described in section 503(g) of the FD&C Act). Federal Food Drug & Cosmetics Act § 201(rr)(2), 21 U.S.C. § 321(rr)(2) (2018).

tobacco products.¹²⁴ Notably, the TCA banned the use of all flavors in cigarettes, with the exception of menthol and tobacco.¹²⁵ In enacting the TCA, Congress recognized that flavors, specifically, could make tobacco products more appealing to youth.¹²⁶

While the TCA specifically addressed cigarette, roll-your-own, and smokeless tobacco, it also gave FDA the authority to issue regulations “deeming” other tobacco products as within its jurisdiction.¹²⁷ The TCA requires manufacturers of deemed products to obtain premarket authorization before commercially marketing new tobacco products.¹²⁸ To obtain premarket authorization, a manufacturer must submit to FDA either (1) a premarket tobacco product application (“PMTA”) demonstrating that the product would be appropriate for the protection of the public health; (2) a report establishing that the product is substantially equivalent to a predicate product; or (3) a request for an exemption from the substantial equivalence requirement.¹²⁹

FDA has the authority to take advisory and enforcement actions for violations of the TCA. An advisory action includes a warning letter that notifies an entity that it violated the law and attempts to bring the entity into voluntary compliance.¹³⁰ If an entity continues to not comply after receiving a warning letter, FDA may take enforcement actions. Enforcement actions include civil money penalties (“CMPs”) or a fine, civil injunctions, criminal prosecution, or seizure of tobacco products.¹³¹

A. FDA Began Efforts to Regulate E-Cigarettes After a 2009 Legal Challenge

In April 2009, two importers and distributors of e-cigarettes sought to enjoin FDA from denying entry of their products into the United States.¹³² FDA barred the products

¹²⁴ Family Smoking Prevention and Tobacco Control Act, Pub. L. No. 111-31, pmb., 123 Stat. 1776 (2009). The TCA specifically directed the Secretary of HHS to establish a Center for Tobacco Products within FDA to implement these authorities. 21 U.S.C. § 387a(e) (2018).

¹²⁵ 21 U.S.C. § 387g(a)(1)(A). Other significant provisions in the law include: (1) the authority to issue product standards, which empower FDA to issue standards to control the levels of chemicals in tobacco products; (2) the authority to issue orders regarding the marketing of new products, which would require a manufacturer to seek an order from FDA prior to marketing a new product; (3) the authority to issue orders for “Modified Risk Tobacco Products,” which would bar manufacturers from introducing products with potentially misleading labels like “light” or “low-tar” without FDA approval; (4) the authority to demand health information from manufacturers regarding the health effects of any tobacco products; and (5) the authority to restrict tobacco marketing and sales to minors. See generally § 387(g).

¹²⁶ H. Comm. on Energy & Com., Family Smoking Prevention and Tobacco Control Act, H.R. Rep. No. 111-58, pt. 1, at 4 (2009), as reprinted in 2009 U.S.C.C.A.N. 468, 470.

¹²⁷ 21 U.S.C. §§ 387–387u.

¹²⁸ 21 U.S.C. §§ 387j(a)(1)–(2), j(b)(1). A new tobacco product is either a product marketed in the United States on or after February 15, 2007, or any modification to a product commercially marketed after February 15, 2007. 21 U.S.C. § 387j. If a predicate product existed prior to February 15, 2007, applicants can apply through a less burdensome process. *Id.*

¹²⁹ 21 U.S.C. §§ 387j(a)(2)(A)(i)–(ii), 387j(b)–(c), 387e(j)(1), 387e(j)(3).

¹³⁰ U.S. FOOD & DRUG ADMIN., *Ensuring Compliance with the Tobacco Control Act and Enforcing the Law*, <https://www.fda.gov/tobacco-products/about-center-tobacco-products-ctp/ensuring-compliance-tobacco-control-act-and-enforcing-law>.

¹³¹ *Id.*

¹³² See *Sottera, Inc. v. Food & Drug Admin.*, 627 F.3d 891 (D.C. Cir. 2010).

from entering the country, asserting that the e-cigarettes appeared to be unapproved drug-device combinations intended to help treat nicotine withdrawal symptoms and were thus illegal under the FD&C Act.¹³³ The companies argued that the products were not intended to treat withdrawal symptoms and therefore could not be regulated by FDA as drug-device products.¹³⁴

In December 2010, the United States Court of Appeals for the District of Columbia Circuit affirmed a lower court ruling in favor of the e-cigarette companies. The courts agreed that FDA could regulate e-cigarettes as a tobacco product under the TCA, but not as a drug-device under the FD&C Act.¹³⁵ As a result, the courts shaped FDA's regulatory power: it can regulate the general use of tobacco products under the TCA, and it can regulate products—including tobacco products—marketed with specific claims of therapeutic effect under the FD&C Act.¹³⁶

As noted above, the TCA as enacted covered cigarettes and certain other types of tobacco; it did not directly address e-cigarettes. The TCA, however, permitted FDA to “deem” products derived from tobacco as within its jurisdiction. In light of the court decision, on April 25, 2011, FDA announced that it planned to “deem” e-cigarettes, among other products, as subject to the TCA through a rule change—ultimately known as the “deeming rule.”¹³⁷ Richard Turman, who served as Deputy Director of FDA's Center for Tobacco Products (“CTP”) from June 2012 to May 2018, told the Subcommittee that although FDA announced the proposed rule change in April 2011, he recalled the changes were under development since 2010.¹³⁸

The deeming rule was among the federal government's top public health priorities. Former CTP Director Mitch Zeller told the Subcommittee that one of his tasks when he became Director in March 2013 “was to do anything [he] could to move deeming along.”¹³⁹ Similarly, Mr. Turman recalled the deeming rule being a focus of keen interest for FDA and CTP and a top regulatory priority.¹⁴⁰ Former Administrator of the Office of Information and Regulatory Affairs (“OIRA”) at the Office of Management and Budget (“OMB”) Howard Shelanski also told the Subcommittee that the rule was an

¹³³ *Id.* at 893.

¹³⁴ *Id.* at 896.

¹³⁵ *Id.* The court cited the U.S. Supreme Court's decision in *Food & Drug Admin. v. Brown & Williamson*, which held that the FD&C Act did not permit FDA to regulate tobacco products as “customarily marketed” because the products are not drugs, devices, or combination products. *Id.*

¹³⁶ *Cf. id.*

¹³⁷ Associated Press, *Regulator Will Treat E-Cigarettes Like Tobacco*, N.Y. TIMES (Apr. 25, 2011), <https://www.nytimes.com/2011/04/26/business/26tobacco.html>.

¹³⁸ Interview with Richard Turman, former Deputy Dir., Ctr. for Tobacco Prods., U.S. Food & Drug Admin. (Nov. 7, 2019) [hereinafter Turman Interview (Nov. 7, 2019)]. FDA's initial focus when drafting the deeming rule was on cigars, but the court's rejection of FDA's attempt at regulating e-cigarettes made e-cigarettes an additional focus. *Id.*

¹³⁹ Briefing with Mitch Zeller, then-Director, Ctr. for Tobacco Prods., U.S. Food & Drug Admin. (July 25, 2019) [hereinafter Zeller Briefing (July 25, 2019)].

¹⁴⁰ Turman Interview (Nov. 7, 2019).

important priority for former FDA Commissioner Margaret Hamburg, U.S. Department of Health and Human Services (“HHS”), and the Obama Administration.¹⁴¹

FDA published an initial version of the proposed deeming rule on April 25, 2014—exactly three years after FDA announced its intent to regulate e-cigarettes as tobacco products.¹⁴² Under the rule, FDA proposed to prohibit the sale of “covered tobacco products” to individuals under the age of 18 and to require the display of health warnings on product packages and in advertisements.¹⁴³ As discussed below, FDA also invited comments on the connection between flavored e-cigarettes and youth usage. Comments were to be collected over a 75-day period ending on July 9, 2014.¹⁴⁴ Ultimately, according to Mr. Turman, FDA was satisfied with the proposed rule.¹⁴⁵

B. FDA Published the Final Deeming Rule in May 2016

On May 10, 2016, FDA issued the final deeming rule, pulling e-cigarettes within FDA’s enforcement jurisdiction.¹⁴⁶ As of August 8, 2016, the effective date of the rule, manufacturers and sellers of newly deemed products were required to register products with and disclose ingredients to FDA, prohibited from using unsubstantiated health claims, and prohibited from selling products to persons under the age of 18.¹⁴⁷ Notably, as explained below, language that would have required flavored e-cigarette products to be removed from the market within a short time frame unless and until approved by FDA was not included in the final deeming rule.

II. OTHER FEDERAL AGENCIES PROVIDED INPUT ON THE TOBACCO DEEMING RULE

FDA led the development of the deeming rule, but other federal agencies provided input on the proposed rule as part of the interagency review process. In particular, aside from FDA and HHS, the key federal entities involved in the deeming rule were OIRA within OMB, the Small Business Administration Office of Advocacy (“SBA OA”), and the Domestic Policy Council (“DPC”). The following section includes

¹⁴¹ Mr. Shelanski served in this role from 2013 to 2017. See GEORGETOWN LAW, *Professor of Law Howard Shelanski*, <https://www.law.georgetown.edu/faculty/howard-shelanski/> (last visited Jan. 26, 2024); Interview with Howard Shelanski, former Adm’r Off. Info. & Regul. Affs., Off. of Mgmt. & Budget (Apr. 9, 2020) [hereinafter Shelanski Interview (Apr. 9, 2020)].

¹⁴² Deeming Tobacco Products To Be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Regulations on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products, 79 Fed. Reg. 23,142 (proposed Apr. 25, 2014) (to be codified at 21 C.F.R. pt. 1100, 1140, 1143).

¹⁴³ *Id.*

¹⁴⁴ *Id.*

¹⁴⁵ Turman Interview (Nov. 7, 2019).

¹⁴⁶ Deeming Tobacco Products to be Subject to the Federal Food, Drug and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Restrictions on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products, 81 Fed. Reg. 28,974, 28,976 (May 10, 2016) [hereinafter Deeming Rule].

¹⁴⁷ *Id.*

background information on these entities' roles in the regulatory process.¹⁴⁸

A. Office of Information and Regulatory Affairs within the Office of Management and Budget

Pursuant to Executive Order 12866 (“E.O. 12866”), OIRA, an office within OMB, is responsible for coordinating interagency review of “significant” regulations before publication.¹⁴⁹ OIRA is comprised of six broad subject matter branches led by branch chiefs, including one dedicated to food, health, and labor that at the time of the Subcommittee’s briefing with OMB reviewed proposed rules from most of HHS, including FDA.¹⁵⁰

E.O. 12866 notes, however, that “[b]ecause [f]ederal [a]gencies are the repositories of significant substantive expertise and experience, [the agencies] are responsible for developing regulations and assuring that the regulations are consistent with applicable law, the President’s priorities, and the principles set forth in th[e] Executive order.”¹⁵¹ To that end, OIRA facilitates the agencies’ review, and OIRA desk officers, who lead the interagency rule review, work to accommodate agencies’ interests and, where necessary, work to develop a path forward taking into account the range of interests.¹⁵² OIRA also works to ensure that agencies comply with the principles in E.O. 12866, which include incorporating public comment, considering alternatives to the rulemaking, and assessing the costs and benefits of the proposed rule.¹⁵³

OIRA also meets with third parties during the review process, pursuant to E.O. 12866, although it does not solicit meetings.¹⁵⁴ According to OIRA, its “policy is to meet with any party interested in discussing issues on a rule under review.”¹⁵⁵ OIRA officials, however, do not affirmatively engage with meeting participants on the merits of a rule; rather, they listen to the participants’ concerns and may ask questions for clarification. Previous OIRA officials informed the Subcommittee that the agency does not draft formal memoranda or other documentation memorializing these meetings.¹⁵⁶

After reviewing all relevant materials, including meetings with third parties and

¹⁴⁸ Executive Order 12866, “Regulatory Planning and Review,” issued by President Clinton on September 30, 1993, establishes and governs the process under which OIRA reviews agency draft and proposed final regulatory actions before they take effect. On the part of the agencies, Executive Order 12866 requires an analysis of the costs and benefits of rules and, to the extent permitted by law, action only on the basis of a reasoned determination that the benefits justify the costs. The Executive Order also generally guides agency participation in finalization of the rule. OFF. INFO. & REGUL. AFFS., OFF. OF MGMT. & BUDGET, *Frequently Asked Questions - Regulations and the Rulemaking Process*, <https://www.reginfo.gov/public/jsp/Utilities/faq.myjsp> (last visited Jan. 26, 2024).

¹⁴⁹ *Id.*

¹⁵⁰ Briefing with Office of Management & Budget (Oct. 24, 2019).

¹⁵¹ *Id.*

¹⁵² *Id.*

¹⁵³ *Id.*

¹⁵⁴ *Id.*

¹⁵⁵ OFF. INFO. & REGUL. AFFS., *Frequently Asked Questions*, *supra* note 148.

¹⁵⁶ Briefing with Office of Management & Budget (Oct. 24, 2019).

input from other agencies, OIRA provides edits and comments from interagency reviewers to the authoring agency in the form of “passbacks.”¹⁵⁷ Where an agency proposes to strike particular language, Mr. Shelanski told the Subcommittee that OIRA generally defers to the agency’s decision unless the functioning of the rule depended on the language.¹⁵⁸ In addition, he noted that OIRA is not a legal review agency. Instead, the authoring agency’s office of general counsel, the OMB general counsel, the White House Counsel’s Office, or DOJ’s Office of Legal Counsel make high-level legal decisions.¹⁵⁹

B. Small Business Administration Office of Advocacy

SBA OA is an independent office within the SBA that represents the views of small businesses to Congress, the White House, federal agencies, federal courts, and state policymakers.¹⁶⁰ Led by a presidentially-nominated, Senate-confirmed Chief Counsel for Advocacy, SBA OA’s functions include: (1) serving as the main recipient of critiques of policies and activities of federal agencies that impact small businesses; (2) counseling small businesses on how to resolve questions and problems concerning the relationship of the small business to the federal government; (3) developing proposals for changes in the policies and activities of any federal agency that will fulfill the purposes of the Small Business Act; (4) representing the views of small entities in federal rulemaking; and (5) coordinating dissemination of information about federal programs and services that benefit small businesses.¹⁶¹

The Chief Counsel is also responsible for monitoring and reporting agencies’ compliance with the Regulatory Flexibility Act of 1980 (“RFA”).¹⁶² The RFA requires federal agencies to assess the impact of their forthcoming regulations on small businesses, small governmental jurisdictions, and certain small not-for-profit organizations.¹⁶³ According to SBA OA, the RFA “does not seek preferential treatment for small entities, require agencies to adopt regulations that impose the least burden on small entities, or mandate exemptions for small entities.”¹⁶⁴ Rather, the RFA “requires agencies to examine public policy issues using an analytical process that identifies, among other things, barriers to small business competitiveness and seeks a level playing field for small entities, not an unfair advantage.”¹⁶⁵

Under the RFA, federal agencies must prepare a regulatory flexibility analysis

¹⁵⁷ *Id.*

¹⁵⁸ Shelanski Interview (Apr. 9, 2020).

¹⁵⁹ *Id.*

¹⁶⁰ OFF. ADVOC., U.S. SMALL BUS. ADMIN., FISCAL YEAR 2021 CONG. BUDGET JUSTIFICATION AND FISCAL YEAR 2019 ANNUAL PERFORMANCE REPORT 2 (2020).

¹⁶¹ Small Business Amendments of 1974, Pub. L. No. 93-386, 88 Stat. 742; see also Pub. L. No. 94-305, 90 Stat. 667.

¹⁶² 5 U.S.C. §§ 601–12 (2018).

¹⁶³ 5 U.S.C. § 603.

¹⁶⁴ OFF. ADVOC., U.S. SMALL BUS. ADMIN., A GUIDE FOR GOVERNMENT AGENCIES: HOW TO COMPLY WITH THE REGULATORY FLEXIBILITY ACT 1 (2012).

¹⁶⁵ *Id.*

when they issue certain proposed and final rules if the head of the issuing agency determines that the proposed rule would have a “significant economic impact on a substantial number of small entities.”¹⁶⁶ The analysis must describe, among other things: (1) the reasons why the regulatory action is being considered; (2) the small entities to which the proposed rule will apply and, when feasible, an estimate of the number of small entities impacted; (3) the projected reporting, recordkeeping, and other compliance requirements of the proposed rule; and (4) any significant alternatives to the rule that would accomplish the statutory objectives while minimizing the impact on small entities.¹⁶⁷ Alternatively, an agency head must certify that the rule would not have a “significant economic impact on a substantial number of small entities,” although the RFA does not define these terms.¹⁶⁸

C. Domestic Policy Council

DPC is part of the Executive Office of the President (“EOP”).¹⁶⁹ The executive order that established DPC explained that its principal functions include: (1) coordinating the domestic policy-making process; (2) coordinating domestic policy advice to the President; and (3) ensuring domestic policy decisions and programs are consistent with the President’s stated goals, and ensuring that the EOP effectively pursues those goals.¹⁷⁰ Moreover, all executive branch agencies are required to “coordinate domestic policy” through DPC.¹⁷¹

According to Cecilia Muñoz, who served as Director of DPC from 2012 to 2017, DPC became involved in rules that it deemed to be “substantial matters of policy.”¹⁷² Although the determination as to whether a rule concerned a “substantial matter of policy” was not systematic, the rule would have to signal a substantial policy shift, have a large impact, garner significant public attention, or be a substantial decision by the Administration.¹⁷³ Ms. Muñoz said that one of her responsibilities was to discern when DPC needed to engage in consideration of a rule.¹⁷⁴ In evaluating a rule, DPC did not get into “the procedural weeds” and did not determine whether an agency had complied with the RFA because that analysis was handled by OIRA.¹⁷⁵ Instead, DPC focused on the “big picture.”¹⁷⁶ Ms. Muñoz also told the Subcommittee that it was not DPC’s role to oppose or support a particular decision.¹⁷⁷ Instead, DPC’s role—and her role as Director—was to ensure each issue was thoroughly vetted and that those agencies,

¹⁶⁶ 5 U.S.C. §§ 601–12.

¹⁶⁷ 5 U.S.C. § 603.

¹⁶⁸ See MAEVE CARY, CONG. RSCH. SERV., RL34355, THE REGULATORY FLEXIBILITY ACT: IMPLEMENTATION ISSUES AND PROPOSED REFORMS 1 (2011).

¹⁶⁹ Exec. Order No. 12,859, 58 Fed. Reg. 44,101 (Aug. 19, 1993).

¹⁷⁰ *Id.*

¹⁷¹ *Id.*

¹⁷² Interview with Cecilia Muñoz, former Dir. Domestic Pol’y Council, Exec. Off. of the President (Mar. 17, 2020) [hereinafter Muñoz Interview (Mar. 17, 2020)].

¹⁷³ *Id.*

¹⁷⁴ *Id.*

¹⁷⁵ *Id.*

¹⁷⁶ *Id.*

¹⁷⁷ *Id.*

members of the Cabinet, and leaders across the Administration with interest in the rule had their perspectives heard.¹⁷⁸ She stressed that, ultimately, the Executive Branch speaks in one voice, as one administration, under one President.¹⁷⁹

Under Ms. Muñoz, DPC did not follow a standard process when reviewing a rule.¹⁸⁰ In some cases, she heard from stakeholders prior to the submission of a rule to OIRA.¹⁸¹ However, once an agency submitted the rule to OIRA, DPC almost always met with stakeholders through the E.O. 12866 process run by OIRA.¹⁸² If other offices within the EOP had concerns about the rule, they would generally raise those concerns at a staff level and then escalate them to Ms. Muñoz.¹⁸³

III. THE FEDERAL GOVERNMENT MISSED AN OPPORTUNITY TO CURB YOUTH E-CIGARETTE USE WHEN IT CHOSE NOT TO ADDRESS FLAVORED E-CIGARETTE PRODUCTS IN THE FINAL DEEMING RULE

The federal government missed an opportunity to curb the rise in youth e-cigarette use when it chose not to address flavored e-cigarette products in the tobacco deeming rule. It did so because federal officials perceived insufficient data demonstrating a link between flavored e-cigarette products and youth usage, and instead prioritized data that showed potential negative economic consequences for small businesses and the broader vaping industry. SBA OA played a significant role in conveying industry concerns and data for the latter point. After officials removed language addressing flavored e-cigarette products, youth e-cigarette use grew dramatically.

A. FDA Sought to Address Flavored Products and Youth Usage, Among Other Issues

Public health officials had several pressing issues in mind when developing the deeming rule. Prior to 2014, Ms. Muñoz recalled concerns from then-HHS Secretary Kathleen Sebelius about the tobacco industry marketing to children and products that clearly appealed to youth.¹⁸⁴ FDA was also aware of the increasing popularity of e-cigarettes among youth between 2012 and 2014.¹⁸⁵ By 2014, e-cigarettes were the most commonly used tobacco product among U.S. youth.¹⁸⁶ FDA, however, did not see a spike in youth e-cigarette use until the 2015 NYTS.¹⁸⁷ Although the 2015 NYTS showed a decline in combustible cigarette use among high school students, total youth tobacco use had “frighteningly” increased due to e-cigarette use.¹⁸⁸ As a result, Mr.

¹⁷⁸ *Id.*

¹⁷⁹ *Id.*

¹⁸⁰ *Id.*

¹⁸¹ *Id.*

¹⁸² *Id.*

¹⁸³ *Id.*

¹⁸⁴ *Id.*

¹⁸⁵ Zeller Briefing (July 25, 2019).

¹⁸⁶ Arrazola et al., *supra* note 74.

¹⁸⁷ Zeller Briefing (July 25, 2019).

¹⁸⁸ Turman Interview (Nov. 7, 2019).

Turman explained that FDA wanted to prevent youth use of nicotine products, while balancing this concern against the role certain nicotine products could play in promoting smoking cessation.¹⁸⁹

Related to youth e-cigarette use was the issue of flavored tobacco products.¹⁹⁰ Mr. Turman informed the Subcommittee that FDA was aware of evidence that flavors were particularly attractive to youth, which tobacco companies referred to as “replacement customers” for individuals who died from tobacco-related illnesses.¹⁹¹ He added that manufacturers used flavors to reduce the harshness of tobacco and nicotine to make products more appealing to users.¹⁹² As tobacco companies stopped selling flavored cigarettes, flavored cigars came on the market.¹⁹³ When e-cigarettes appeared, they were also flavored. Mr. Shelanski described one of the initial goals of the deeming rule as eliminating highly addictive and high-level nicotine products that came in a “huge range of flavors.”¹⁹⁴ The deeming rule represented the first time FDA would be able to “sweep” those flavors into the regulatory framework “and get rid of those flavorings.”¹⁹⁵

Mr. Turman acknowledged that, to address these issues in the proposed deeming rule, FDA needed to be “up on the science.”¹⁹⁶ He explained that it took several years to propose the deeming rule, in part, because the science continued to evolve, and FDA constantly received new data.¹⁹⁷ He also emphasized that FDA knew any regulation under the TCA would prompt a court challenge, especially because it was a “first blush” action by FDA.¹⁹⁸ This reality underscored the importance of FDA basing the deeming rule on solid scientific evidence.¹⁹⁹

1. FDA Solicited Comments on Flavored E-cigarettes

On April 25, 2014, FDA formally invited comments on, among other issues, the long-term effects of flavored tobacco product usage and the public health effects of e-cigarettes.²⁰⁰ FDA stated that it was “aware that some tobacco products, such as e-cigarettes . . . are being marketed with . . . flavors, and that these flavors can be especially attractive to youth.”²⁰¹ It also noted “the increase in e-cigarette use by youth

¹⁸⁹ *Id.*

¹⁹⁰ *Id.*

¹⁹¹ *Id.* Mr. Zeller confirmed that FDA received many comments from individuals highlighting the dangers of e-cigarettes but also received comments arguing that flavors were important in helping smokers switch from combustible cigarettes to e-cigarettes. Zeller Briefing (July 25, 2019).

¹⁹² Turman Interview (Nov. 7, 2019).

¹⁹³ *Id.*

¹⁹⁴ Shelanski Interview (Apr. 9, 2020).

¹⁹⁵ *Id.*

¹⁹⁶ Turman Interview (Nov. 7, 2019).

¹⁹⁷ *Id.*

¹⁹⁸ *Id.*

¹⁹⁹ *Id.*

²⁰⁰ 79 Fed. Reg. 23,141 at 23,142.

²⁰¹ *Id.*

and the availability of fruit and candy-flavored e-cigarette liquid.”²⁰² FDA therefore requested comments on whether it should extend the prohibition against flavors in cigarettes to other tobacco products.²⁰³

SBA OA filed comments with FDA on June 11, 2014. Primarily, SBA OA requested that FDA issue a supplemental Initial Regulatory Flexibility Analysis (“IRFA”) because it viewed the IRFA in FDA’s April 2014 publication as lacking essential information necessary to inform FDA’s decisions.²⁰⁴ FDA’s IRFA included an analysis of one alternative cost-saving measure for small businesses—not deeming premium cigars as covered tobacco products.²⁰⁵ SBA OA encouraged FDA “to apply this analysis elsewhere in the IRFA so that not deeming other product categories can be considered and comprehensively discussed.”²⁰⁶ Importantly, SBA OA made no mention of the issue of flavors; nor did it tie removing flavored products from the market to business closings or job losses.²⁰⁷

According to one FDA official, FDA received and considered over 135,000 comments “from tobacco product manufacturers, retailers, academia, medical professionals, local governments, advocacy groups, and consumers.”²⁰⁸ A large share of those comments consisted of write-in campaigns, including: (1) commenters who claimed e-cigarettes saved their lives; (2) commenters who supported regulating flavored tobacco products and called for “additional measures banning candy and fruit flavored tobacco products [including e-cigarettes]”; (3) commenters who advocated for “a world without flavored tobacco”; and (4) commenters who supported “a ban on flavored tobacco.”²⁰⁹ FDA also received web-based write-in campaigns calling for banning or regulating flavored e-cigarettes, although other campaigns promoted e-cigarettes as an effective cessation device.²¹⁰ Notably, FDA received requests from state and local authorities, including the Delaware Department of Health and Social Services, to regulate flavored, non-combustible tobacco products.²¹¹

2. Based on the Comments, FDA’s Proposed Rule Would Have Required Flavored E-cigarettes to Be Removed from the Market

After considering and addressing the comments received, FDA sent its proposed

²⁰² *Id.*

²⁰³ *Id.*

²⁰⁴ Letter from Winslow Sargeant, Chief Couns. for Advoc., and Dillon Taylor, Assistant Chief Couns. for Advoc., to The Hon. Margaret A. Hamburg (June 11, 2014).

²⁰⁵ 79 Fed. Reg. 23,141 at 23,195–97.

²⁰⁶ Letter from Winslow Sargeant, Chief Couns. for Advoc., and Dillon Taylor, Assistant Chief Couns. for Advoc., to The Hon. Margaret A. Hamburg (June 11, 2014).

²⁰⁷ *Id.*

²⁰⁸ See Gerie Voss, Off. of Regul., Ctr. for Tobacco Prods., U.S. Food & Drug Admin., *Final Rule - Tobacco Products Deemed to be Subject to the Federal Food, Drug, & Cosmetic Act (“Deeming Rule”)* (2016), <https://www.federalregister.gov/documents/2016/05/10/2016-10685/deeming-tobacco-products-to-be-subject-to-the-federal-food-drug-and-cosmetic-act-as-amended-by-the>.

²⁰⁹ PortENDS-011865–80.

²¹⁰ *Id.*

²¹¹ PortENDS-122304–06.

deeming rule to OMB on October 19, 2015.²¹² The rule included a section that stated FDA would not be extending enforcement discretion for newly regulated flavored tobacco products, including e-cigarettes, and would have required these flavored products to be removed from the market 90 days after the effective date of the rule—by November 2016.²¹³ Specifically, the proposed rule stated:

Given the attractiveness of flavors, especially to youth and young adults, and the impact flavored tobacco products may have on youth initiation, the [FDA] is not extending its compliance policy for premarket review to flavored new tobacco products. Retailers of flavored tobacco products will have an additional 90 days following the effective date of this rule to sell off any existing inventory. Consequently, as of 180 days after publication of the rule, any non-grandfathered, newly deemed flavored tobacco products on the market will be subject to enforcement.²¹⁴

Flavored products could re-enter the market once they received pre-market approval from FDA.²¹⁵ This would have required manufacturers to submit PMTAs containing studies showing the health risks of their tobacco products and whether such products present less risk than other tobacco products; a complete list of ingredients; the methods used in manufacturing the product; and a demonstration of compliance with the applicable tobacco product standards.²¹⁶ In effect, the provision would have required all flavored e-cigarette products to be removed from the market until approved by FDA.

In support of its proposal, FDA dedicated almost 15 pages of the proposed rule to discussing relevant studies and other information it received from commenters.²¹⁷ These pages addressed the rise in e-cigarette usage, the attractiveness of flavored tobacco products generally, and the attractiveness of flavored tobacco products to youth, specifically.²¹⁸ According to FDA, comments and data supported several findings, including: (1) flavors make tobacco products easier to use and increase their appeal; (2) millions of youth use flavored tobacco products, including e-cigarettes; and (3) youth and young adult use of tobacco products that are often flavored, including e-cigarettes, had risen dramatically. FDA also highlighted studies showing that youth and young adult tobacco users were more likely to use flavored tobacco products—including

²¹² OFF. INFO. & REGUL. AFFS., OFF. OF MGMT. & BUDGET, *OIRA Conclusion of EO 12866 Regulatory Review*, <https://www.reginfo.gov/public/do/eoDetails?rrid=125649> (showing a received date of Oct. 19, 2015).

²¹³ U.S. FOOD & DRUG ADMIN., DEEMING FINAL RULE REDLINE CHANGES (May 27, 2016), <https://www.regulations.gov/document?D=FDA-2014-N-0189-83193>; Interview with Mitch Zeller, then-Dir., Ctr. for Tobacco Prods., U.S. Food & Drug Admin. (July 2, 2020) [hereinafter Zeller Interview (July 2, 2020)].

²¹⁴ PortENDS-028557.

²¹⁵ PortENDS-028557–59.

²¹⁶ PortENDS-028381 (citing Section 910(b)(1) of the FD&C Act).

²¹⁷ PortENDS-028559–72.

²¹⁸ *Id.*

e-cigarettes—than adult tobacco users and that certain chemical flavorings in e-cigarettes contain toxic compounds.²¹⁹ FDA concluded:

Based on the comments and emerging data regarding the impact of flavors on youth and young adult tobacco product initiation and long-term use, as well as concerns regarding the existence of toxic compounds in some tobacco product flavorings, FDA has decided not to include flavored tobacco products within the compliance policy for premarket review requirements.²²⁰

B. FDA’s Proposed Deeming Rule Prompted Concerns from Industry and Federal Agencies

FDA’s submission of the proposed rule to OIRA triggered the interagency review period. In accordance with E.O. 12866, OIRA received a high volume of requests for meetings related to the deeming rule. Interested parties included public health advocates and industry representatives, as well as other concerned citizens.²²¹ Other federal entities raised concerns about the evidence underlying FDA’s proposal to remove flavored e-cigarettes from the market.

1. Industry Flagged Economic Concerns

FDA’s proposed rule prompted extensive feedback from interested parties, including from members of the vaping industry. SBA OA was particularly active in representing industry, with Mr. Turman describing them as “fierce advocates.”²²² For example, one SBA OA representative attended 52 meetings with OIRA personnel, which the SBA OA Director of Interagency Affairs described to the Subcommittee as “a high number” of E.O. 12866 meetings for these types of deliberations.²²³ The last six of these meetings were exclusively with members of the vaping industry.²²⁴

Notably, none of the officials that the Subcommittee interviewed recalled e-cigarette industry representatives raising extensive concerns about FDA’s proposed actions on flavored products. Mr. Shelanski recalled “substantial lobbying” on the proposed rule but stated that this came from the premium cigar industry, which argued

²¹⁹ *Id.*

²²⁰ PortENDS-028559–60.

²²¹ Deeming Rule, 81 Fed. Reg. 28,974 at 28,982; OFF. INFO. & REGUL. AFFS., OFF. OF MGMT. & BUDGET, *EO 12866 Meetings Search Results*, <https://www.reginfo.gov/public/do/eom12866SearchResults?pubId=201604&rin=0910-AG38&viewRule=true>. Mr. Shelanski recalled that OIRA also met with the tobacco industry, including cigar manufacturers, the American Medical Association, the American Lung Association, and other groups. Shelanski Interview (Apr. 9, 2020).

²²² Turman Interview (Nov. 7, 2019).

²²³ Briefing with Small Business Administration Office of Advocacy (Oct. 10, 2019); OFF. ADVOC., U.S. SMALL BUS. ADMIN., *12866 Meetings for the Deeming Rule Attended by Dillon Taylor* (on file with the Subcommittee); see also ADV002001–02.

²²⁴ OFF. ADVOC., U.S. SMALL BUS. ADMIN., *12866 Meetings for the Deeming Rule Attended by Dillon Taylor* (on file with the Subcommittee); see also ADV002001–02.

for an exemption for their particular products.²²⁵ Similarly, Ms. Muñoz believed “almost none” of the feedback from the E.O. 12866 meetings concerned flavors, and to the extent flavors were discussed, it was after OMB raised the topic at DPC’s request.²²⁶ Likewise, former HHS Secretary Sylvia Burwell told the Subcommittee that, at this point, five years after the events in question, she did not recall attending any meetings in which she was “informed that the flavor language in the draft rule was of particular concern to members of the public” and that her only general recollection of public concern relating to the deeming rule “largely related to the regulation of cigars.”²²⁷

Records provided to the Subcommittee show that several E.O. 12866 meetings that SBA OA attended touched on flavored e-cigarette products. Participants at these meetings included vaping industry members such as NJOY, the American E-Liquid Manufacturing Standards Association, the Tobacco Vapor Electronic Cigarette Association, and the Vaping Industry Alliance.²²⁸ Still, the SBA OA Director of Interagency Affairs noted to the Subcommittee that SBA OA never identified the proposed flavor language as an area of particular concern.²²⁹

According to Mr. Shelanski, the vaping industry’s primary concern was the proposed rule’s requirement that manufacturers submit a PMTA or a report demonstrating substantial equivalence to a predicate product.²³⁰ Under the proposed deeming rule, a vape shop had 90 days to submit its application or report to continue selling their products.²³¹ Members of the vaping industry argued that there were not many e-cigarette products on the market as of February 2007, such that e-cigarettes were not likely to meet a substantial equivalence test. Thus, manufacturers would need to submit a PMTA, which were long, detailed applications. Vape shops and other small businesses in the industry argued that the timeline and PMTA standards would be particularly onerous for small vaping companies, as opposed to large tobacco companies; this raised the concern that the deeming rule would deliver the e-cigarette market into the hands of the largest, well-established industry players.²³² Small businesses in the vaping industry warned that the product standards would have a negative economic impact, leading to business closures and job losses across the United States.²³³ Mr. Shelanski remembered receiving data showing around 8,000 to 11,000 small vape shops operating in the United States in 2015, with more opening

²²⁵ Shelanski Interview (Apr. 9, 2020).

²²⁶ Muñoz Interview (Mar. 17, 2020).

²²⁷ Statement of Sylvia Burwell, former Sec’y U.S. Dep’t Health & Hum. Servs., to the Subcommittee (Aug. 3, 2020) [hereinafter Burwell Statement (Aug. 3, 2020)].

²²⁸ OFF. ADVOC., U.S. SMALL BUS. ADMIN., *12866 Meetings for the Deeming Rule Attended by Dillon Taylor* (on file with the Subcommittee); see also ADV002001–02.

²²⁹ Briefing with Small Business Administration Office of Advocacy (Oct. 10, 2019).

²³⁰ Shelanski Interview (Apr. 9, 2020). As noted above, manufacturers, distributors, and retailers that market products could be subject to civil injunctions and/or criminal prosecutions for marketing products without proper FDA authorization. FDA could also seize the marketed products. 21 U.S.C. § 387j.

²³¹ Shelanski Interview (Apr. 9, 2020).

²³² *Id.*

²³³ Interview with Allison Orris, former Assoc. Adm’r Off. Info. & Regul. Affs., Off. of Mgmt & Budget (Dec. 2, 2019) [hereinafter Orris Interview (Dec. 2, 2019)]; Shelanski Interview (Apr. 9, 2020).

every day.²³⁴ He recalled SBA OA urging: “Whatever you do, don’t kill small businesses.”²³⁵

2. Federal Officials Questioned and Weighed the Need to Act on Flavored Products

Although industry did not flag the proposed flavor language as a major area of concern, the flavor language did generate discussion among federal entities. Mr. Shelanski recalled significant discussion on the flavor issue during meetings with OIRA and other government officials.²³⁶ He and other officials were “simply amazed” at the range of flavors and flavor-related advertisements for tobacco products.²³⁷ In particular, Mr. Shelanski remembered FDA representatives describing that tobacco companies were using flavors “from kids’ candy to flavor tobacco.”²³⁸ He and other officials were skeptical that a full range of flavors, including certain “outlandish concoctions,” was truly necessary.²³⁹ Further, there was “not a lot of sympathy at OIRA or anywhere in the government for the strident arguments that the flavor advocates were making,” and a “general skepticism” that flavored products could help smokers transition from combustible cigarettes.²⁴⁰

Although officials were skeptical of pro-flavor arguments, they also questioned the scientific analysis and empirical data showing who used flavored products, whether flavors were “pulling in kids,” and whether flavors had the effect of expanding the market.²⁴¹ According to Mr. Shelanski, although OIRA had a reasonable fear that flavored e-cigarette products appealed to youth, officials felt the data submitted on this point was limited and unclear and that more data was needed.²⁴² Mr. Shelanski recalled seeking out studies related to flavored tobacco products and the attractiveness of e-cigarettes to new users and particularly underage users.²⁴³ However, OIRA ultimately concluded that the data on the attractiveness of e-cigarettes to youth and young adults was scarce, as was the data demonstrating any beneficial impact removing flavored products would have.²⁴⁴ OIRA reached this conclusion despite the nearly 15 pages FDA included in its proposed deeming rule addressing flavored tobacco products, including e-cigarettes, and the strong connection between these

²³⁴ Shelanski Interview (Apr. 9, 2020).

²³⁵ *Id.*

²³⁶ *Id.*

²³⁷ *Id.*

²³⁸ *Id.*

²³⁹ *Id.* Mr. Shelanski invented the flavor of “cotton candy crème brulee” as an example of an “outlandish” flavor. *Id.*

²⁴⁰ *Id.* Mr. Zeller recalled that the reports FDA received from interested parties relating to the use of e-cigarettes to help adults transition from combustible cigarettes were mostly anecdotal. He described the data on e-cigarette attraction for new and young users as “more solid.” Still, FDA considered anecdotal evidence along with all other information, including quantitative studies identified by the Surgeon General and peer-reviewed qualitative research. Zeller Interview (July 2, 2020).

²⁴¹ Shelanski Interview (Apr. 9, 2020).

²⁴² *Id.*

²⁴³ *Id.*

²⁴⁴ *Id.*

products and the dramatic rise in youth and young adult tobacco use.²⁴⁵ According to Mr. Shelanski, the scientific information he and others reviewed did not appear to support the flavor language.²⁴⁶

In October 2015, DPC also convened a series of three to four “policy process” meetings to hear from agencies and EOP offices with equities related to the rule.²⁴⁷ While DPC was not focused specifically on flavors, Ms. Muñoz felt DPC needed to be involved in the decision-making process because it became apparent that officials would need to make policy judgments based on limited or insufficient scientific and evidentiary data.²⁴⁸ As with OIRA, Ms. Muñoz, who supported consideration of including flavors in the rule from a policy perspective, was concerned about whether there was adequate data to support several aspects of the rule, including flavors, and particularly the lack of data on the impact on small businesses.²⁴⁹ She informed the Subcommittee that in a meeting with FDA, the agency admitted it had incomplete information supporting its proposed flavor language and was essentially making “an educated guess.”²⁵⁰ When asked about this statement, Mr. Zeller told the Subcommittee that he believed Ms. Muñoz’s characterization of FDA’s position was “not accurate” and stated that he did not “remember ever saying” that FDA had made an educated guess.²⁵¹ He stressed that FDA based the deeming rule on the evidence available at the time.²⁵²

Given what she saw as an apparent lack of evidence, Ms. Muñoz requested additional information from OMB, the National Economic Council, SBA, and any other entity that might have information to offer.²⁵³ Ms. Muñoz stated that SBA submitted information showing that the deeming rule would have a devastating impact on small businesses.²⁵⁴ Ms. Muñoz acknowledged, however, that the data in favor of and against the flavor language was “uncertain.”²⁵⁵

C. FDA Officials Believed the Proposed Flavor Language Would Be Included in the Final Deeming Rule

Intense interagency negotiations continued throughout December 2015. Officials recalled meetings in December in which flavors continued to be a topic of discussion.²⁵⁶ FDA requested information related to the appeal of flavors to youth as late as December

²⁴⁵ PortENDS-028559–72.

²⁴⁶ Shelanski Interview (Apr. 9, 2020).

²⁴⁷ Muñoz Interview (Mar. 17, 2020). This group included the National Economic Council, SBA, FDA, and HHS. *Id.*

²⁴⁸ *Id.*

²⁴⁹ *Id.*

²⁵⁰ *Id.*

²⁵¹ Zeller Interview (July 2, 2020).

²⁵² *Id.*

²⁵³ Muñoz Interview (Mar. 17, 2020).

²⁵⁴ *Id.*

²⁵⁵ *Id.*

²⁵⁶ Orris Interview (Dec. 2, 2019); Turman Interview (Nov. 7, 2019); Shelanski Interview (Apr. 9, 2020).

24, 2015, as evidenced in one letter FDA sent to a small tobacco product manufacturer:

Research suggests that flavor has been associated with initiation and continued use [sic] of smokeless tobacco products, particularly among youth and young adults. Although you include information asserting that the differences in . . . flavors do not raise different questions of public health from a toxicological perspective, this information is not sufficient to address whether the change in . . . flavor will cause the new products to be perceived differently or to be more appealing than the predicate product. It is possible that introducing the products with the new flavors may make the products more appealing to consumers than the predicate product. As a result, it is possible that the addition of . . . flavors may raise different questions of public health. In order to assess the new products, we need information about how the changes in . . . flavors impact consumer perceptions and product appeal.²⁵⁷

Although discussion appears to have continued internally on flavors through December 2015, FDA officials informed the Subcommittee that they understood the flavor language would be included in the final deeming rule.²⁵⁸ Notably, in a December 25, 2015 e-mail, Mr. Zeller explained that “[w]ork continued on deeming into last night,” and that “[a]ll remaining substantive issues (Freidman article, cigar count, illicit trade/Canada, PMTA costs, and small business definition/policy) were resolved yesterday.”²⁵⁹ He went on to identify issues raised by SBA and DOJ that remained to be resolved, but the flavor language was not included on that list.²⁶⁰ Mr. Turman informed the Subcommittee that he understood that all issues had been resolved and the deeming rule—including flavors—was final as of the end of December 2015, even though FDA would not publish the rule until January 15, 2016, before the State of the Union address.²⁶¹

D. In Early 2016, HHS Reconsidered the Flavor Language Due to Potential Economic Consequences for Small Businesses

In early 2016, HHS officials notified FDA policy officials that the proposed rule was being reconsidered and instructed FDA to wait before proceeding with the rule.²⁶² HHS officials did not tell FDA officials what issues they were reconsidering, why, or the new anticipated publication date.²⁶³

Correspondence from this period suggests that then-HHS Secretary Burwell and other senior HHS officials were concerned about potential economic consequences

²⁵⁷ ADV002317.

²⁵⁸ Turman Interview (Nov. 7, 2019); Zeller Interview (July 2, 2020).

²⁵⁹ PortENDSFDA-0000378.

²⁶⁰ *Id.*

²⁶¹ Turman Interview (Nov. 7, 2019).

²⁶² *Id.*

²⁶³ *Id.*

from the flavor language specifically.²⁶⁴ In a February 8, 2016 e-mail, for example, a senior HHS official requested economic information assuming vape shops could no longer manufacture flavored liquids.²⁶⁵ The official sent Secretary Burwell a memorandum on February 16, 2016 conveying the information.²⁶⁶

- Size of the Vaping Industry. Drawing on answers from FDA economists, the memorandum first estimated that 5,000 to 10,000 vape shops existed in early 2016, but the economists expressed uncertainty regarding this count due, in part, to limited and outdated government statistics.²⁶⁷
- Potential Job Losses. In response to a question from Secretary Burwell concerning the estimated job losses associated with vape shop closures, FDA economists again expressed uncertainty.²⁶⁸ Nevertheless, the memorandum provided a rough estimate: assuming 80 percent of 8,500 operating vape shops would close following the disappearance of flavored products, and assuming each shop would terminate five employees, 35,000 lost jobs would result.²⁶⁹ Importantly, FDA economists stressed that because vape shops were fairly new businesses, they might actually have a lower average employment of around 2.5 workers, which would result in the loss of only 17,500 jobs.²⁷⁰
- Monetary Impact and Lost Wages. Secretary Burwell also sought to assess the monetary impact of business closures and lost jobs, asking economists to opine on lost wages. FDA's economists stated plainly that FDA could not determine lost wages, including lost employee salaries and lost sales revenues, because of the proposed flavor language.²⁷¹ It cited average annual earnings in retail tobacco stores of around \$19,000 and estimated lost annual earnings due to vape shop closures at somewhere between \$333 million and \$666 million per year, depending on job losses.²⁷² FDA economists also noted, however, that as certain flavored products returned to the market in two to four years through the pre-market review process, vape

²⁶⁴ See, e.g., PortENDSOS-0000772, PortENDSOS-0000774. Similarly, Mr. Zeller told Subcommittee staff that he believed political appointees in the HHS Office of the Secretary had reconsidered the flavor language due to this potential economic impact. Zeller Briefing (July 25, 2019).

²⁶⁵ PortENDSOS-0000772.

²⁶⁶ PortENDSOS-0000774. The memorandum stressed that a lack of strong statistics on vape shops and vape sector employment limited FDA's ability to forecast the impact of the deeming rule on the industry. See Memorandum from Andrea Palm, Senior Couns. to the Sec'y Health & Hum. Servs., to Sylvia Burwell, Sec'y Health & Hum. Servs. (Feb. 12, 2016) (notes on file with the Subcommittee).

²⁶⁷ Memorandum from Andrea Palm, Senior Couns. to the Sec'y Health & Hum. Servs., to Sylvia Burwell, Sec'y Health & Hum. Servs. (Feb. 12, 2016) (notes on file with the Subcommittee).

²⁶⁸ *Id.*

²⁶⁹ *Id.* Five employees per shop was the average employment per retail tobacco store according to the 2013 U.S. Statistics of Business. *Id.*

²⁷⁰ *Id.* The memorandum also noted that total payroll job creation in the United States had averaged 235,000 jobs per month in the two years before February 2016. *Id.*

²⁷¹ *Id.*

²⁷² *Id.*

shops could reopen and industry employment could rise.²⁷³ The economists added that because vape shops were relatively new and small, their closures were unlikely to impose broader economic effects on their communities—apart from broken leases or defaults on business loans.²⁷⁴

- **Alternative Business Models.** Secretary Burwell also asked about the possibility of vape shops transitioning to a retail-only business model.²⁷⁵ In response, FDA economists explained that the disappearance of flavored products would substantially reduce the number of products available to vape retailers.²⁷⁶ Accordingly, the economists again predicted the closure of 80 percent of vape shops after flavored products exited the market, although a much smaller number of vape shops could transition to catering to consumers using tobacco-flavored e-cigarette products.²⁷⁷ The economists also explained that these vape shops could be expected to maintain their pre-deeming rule employment numbers.²⁷⁸
- **Supply Chain.** In response to a question from Secretary Burwell about the impact of the flavor policy on the supply chains that service vape shops, FDA economists noted that the temporary disappearance of flavored e-cigarette products from the market would lower demand for these products.²⁷⁹ The economists noted, however, that producers in the supply chain could experience these changes as slowed growth rather than an absolute decline in sales.²⁸⁰ Moreover, consumer and retail shifts to non-flavored products could partially offset declines due to flavored products leaving the market.²⁸¹
- **Alternative Revenue Streams.** Finally, Secretary Burwell asked whether vape shops had other revenue streams that could sustain them while their products underwent FDA review and returned to the market.²⁸² In response, FDA economists stressed that while they lacked information on diversification strategies for vape shops, certain shops had added cafes, lounges, and other activities to their businesses.²⁸³ FDA economists cautioned, however, that these activities might not sustain businesses that mostly relied on sales of vaping products, which could decline once flavored products exited the market.²⁸⁴

²⁷³ *Id.*

²⁷⁴ *Id.*

²⁷⁵ *Id.*

²⁷⁶ *Id.*

²⁷⁷ *Id.*

²⁷⁸ *Id.*

²⁷⁹ *Id.*

²⁸⁰ *Id.*

²⁸¹ *Id.*

²⁸² *Id.*

²⁸³ *Id.*

²⁸⁴ *Id.*

E. The Federal Government Struck the Flavor Language in the Final Deeming Rule

Ultimately, federal officials struck the flavor language from the final deeming rule published on May 5, 2016. Federal officials appear to have made the decision just a few weeks after Secretary Burwell received the economic analysis discussed above. In an email on March 2, 2016, HHS officials referenced a decision memorandum titled, “Economic Impacts of proposed final deeming rule on e-cigarette vape shops.”²⁸⁵ Relatedly, Mr. Zeller stated to the Subcommittee that the decision to strike the flavor language had occurred by the “first half of March” and that “the agency was [then] working on a new approach to this issue.”²⁸⁶ Correspondence dated March 16, 2016, in which a FDA official shared edits to the deeming rule designed to “reflect the new compliance policy,” demonstrated this change in approach.²⁸⁷ The official “added language to provide a better balance regarding flavored e-cigarettes.”²⁸⁸

Federal officials not only omitted the flavor language, but also the more than 15 pages of evidence detailing the role that flavors played in enticing youth and young adults.²⁸⁹ Instead, FDA stated in the final rule:

[Although] new data shows continued growth in youth and young adult usage of flavored tobacco products, [FDA] has balanced those concerns with preliminary data showing that some adults may potentially use flavored e-cigarettes to transition from combusted tobacco use when developing the compliance policy for premarket review.²⁹⁰

1. Ms. Muñoz Claimed Responsibility for Striking the Flavor Language, but the Subcommittee Did Not Review Official Documentation

The Subcommittee did not review any official record demonstrating which entity or agency made the decision to strike the flavor language. Many of the government officials the Subcommittee interviewed could not recall who made the decision or how federal officials communicated it to stakeholders.

Ms. Muñoz, however, claimed responsibility for the decision to strike the flavor language.²⁹¹ Despite authoring the rule, FDA was not involved in striking the flavor language. Ms. Muñoz confirmed that neither FDA nor HHS were “in the room” when she decided to strike the language, though she had fully considered their input in the process before reaching her ultimate decision.²⁹² Mr. Zeller also recalled that, “at the

²⁸⁵ PortENDSOS-0000474. The Subcommittee did not receive or review the memorandum.

²⁸⁶ Zeller Interview (July 2, 2020).

²⁸⁷ PortENDSFDA-0000470–71.

²⁸⁸ *Id.*

²⁸⁹ Emily Baumgaertner, *The FDA Tried to Ban Flavors Years Before the Vaping Outbreak. Top Obama Officials Rejected the Plan*, L.A. TIMES (Oct. 1, 2019), <https://www.latimes.com/politics/story/2019-10-01/vaping-flavors-obama-white-house-fda>.

²⁹⁰ Deeming Rule, 81 Fed. Reg. 28,974 at 29,055.

²⁹¹ Muñoz Interview (Mar. 17, 2020).

²⁹² *Id.*

end of the day, the decision [was] made for us. . . . This was an instance where the decision came down, and that was basically it.”²⁹³

Ms. Muñoz recalled tasking Mr. Shelanski with communicating the decision back to the agencies.²⁹⁴ Mr. Shelanski, for his part, recalled being told at some point that the “the flavoring ban is out,” although he claimed he could not remember exactly when this conversation occurred or who conveyed the decision.²⁹⁵ He told the Subcommittee that he was not involved in communicating the decision on the flavor language to FDA.²⁹⁶

In two separate conversations with the Subcommittee, Mr. Zeller stated that he believed Secretary Burwell personally opposed the flavor language of the deeming rule and was involved in removing the language.²⁹⁷ Mr. Turman echoed Mr. Zeller’s comments that the decision to strike the flavor language was communicated by HHS political officials to FDA, but he did not know whether the final decision originated from the White House or Secretary Burwell.²⁹⁸ When presented with an assertion from a senior official familiar with the development of the deeming rule that he believed that it was her decision to strike the flavor language in the draft rule, Secretary Burwell responded that the interagency review process “supported issuing the final rule in the form it took when published.”²⁹⁹ She added that the FDA Commissioner “executes FDA’s rule making responsibilities on behalf of the HHS Secretary,”³⁰⁰ and as “HHS’s chief policy manager,” she “supported the decision to issue the deeming rule in the form that best equipped it to withstand any legal challenges.”³⁰¹

2. Officials Prioritized Evidence of Economic Consequences to Small Businesses Over Evidence Tying Flavors to Youth Usage

As with who made the decision, the Subcommittee did not review any official record documenting the basis for striking the flavor language. The former

²⁹³ Zeller Briefing (July 25, 2019).

²⁹⁴ Muñoz Interview (Mar. 17, 2020).

²⁹⁵ Shelanski Interview (Apr. 9, 2020).

²⁹⁶ *Id.*

²⁹⁷ Zeller Interview (July 2, 2020); Zeller Briefing (July 25, 2019).

²⁹⁸ Turman Interview (Nov. 7, 2019). Other individuals interviewed by the Subcommittee did not recall Secretary Burwell playing a central role in the deeming rule. Ms. Orris, for example, stated that she did not remember hearing anything about Secretary Burwell influencing flavor policy. Orris Interview (Dec. 2, 2019). Similarly, Ms. Muñoz did not recall Secretary Burwell being “hugely” engaged or expressing a strong view on issues discussed during the one meeting she recalls Secretary Burwell attending. Muñoz Interview (Mar. 17, 2020). Finally, Mr. Shelanski recalled that instead of advocating for removing flavor language, Secretary Burwell (or other high-level HHS officials) had the “firm view” that all flavors should be banned. Shelanski Interview (Apr. 9, 2020). When Mr. Zeller was told that no other federal official supported his allegation concerning Secretary Burwell’s role, Mr. Zeller responded, “[t]hat remains my opinion. I can’t go into the deliberative process, but that remains my opinion. It is unchanged.” Zeller Interview (July 2, 2020). According to Mr. Zeller, there is a decision document with Secretary Burwell’s signature. Email from Mr. Zeller to the Subcommittee (Feb. 24, 2024). The Subcommittee never received or reviewed such document.

²⁹⁹ Burwell Statement (Aug. 3, 2020).

³⁰⁰ *Id.*

³⁰¹ *Id.*

Administration officials that the Subcommittee interviewed expressed differing views as to why the federal officials struck the flavor language, although most agreed that the evidence of economic consequences for small vaping businesses outweighed the evidence of flavors and youth use of tobacco products. Secretary Burwell, for example, explained to the Subcommittee that although the regulatory record included “preliminary evidence of harm arising from youth use of flavored e-cigarettes,” it also contained “preliminary evidence” that adults used flavored e-cigarettes to transition away from combustible cigarettes.³⁰² She described the evidence of harm and benefit as “ambiguous.”³⁰³ Secretary Burwell also pointed to evidence in the record about “the significant negative economic impacts that [the deeming] rule would have on small businesses.”³⁰⁴

Ms. Muñoz told the Subcommittee that based on input from SBA, she ultimately concluded the impact of the flavor language on small businesses, particularly vaping shops, would be profound, and policymakers lacked sufficient data to suggest this impact was warranted.³⁰⁵ In her view, FDA failed to present sufficient evidence supporting the need for the flavor language and noted that “it did not feel just or appropriate” to go forward with the flavor language and tell a new industry: “Sorry, you have to close doors now because we think something bad might happen, but we are not really sure.”³⁰⁶ Ms. Muñoz also noted that officials discussed alternatives to the language—such as removing only certain flavors—but they ultimately determined there was no empirically supported alternative.³⁰⁷

In contrast to Ms. Muñoz’s characterization of the evidence, Mr. Zeller reiterated to the Subcommittee his belief in the evidence supporting the flavor language.³⁰⁸ Importantly, when asked by Subcommittee staff whether he believed FDA successfully communicated to DPC the evidence supporting the risks of e-cigarettes to youth, which necessitated a flavor language, Mr. Zeller answered “yes.”³⁰⁹ He also described the evidence of the economic impact on vape shops arising from the flavor language as “uncertain” because FDA economists had difficulty finding hard data on the issue.³¹⁰ He noted that FDA accounted for this uncertainty when preparing its Regulatory Impact Analysis and acknowledged that many shops would either go out of business or transform their business model to focus solely on selling finished products.³¹¹ Ultimately, Mr. Zeller viewed FDA’s proposed final rule as a “balancing act” between deterring youth usage of e-cigarettes and ensuring adult access to these products for

³⁰² *Id.*

³⁰³ *Id.*

³⁰⁴ *Id.*

³⁰⁵ Muñoz Interview (Mar. 17, 2020).

³⁰⁶ *Id.*

³⁰⁷ *Id.*

³⁰⁸ Zeller Interview (July 2, 2020) (“We felt there was an evidence-based decision to support the policy embodied in the draft final rule.”).

³⁰⁹ *Id.*

³¹⁰ *Id.*

³¹¹ *Id.* Mr. Turman did not recall seeing any analysis supporting the position that potential economic impact of the flavor language outweighed its potential health benefits. Turman Interview (Nov. 7, 2019).

transitioning away from combustible cigarettes.³¹²

Officials also expressed concern that, given the limited supporting evidence, including the flavor language would render the entire deeming rule vulnerable to “a successful legal challenge” under the Administrative Procedure Act.³¹³ Specifically, officials feared that an industry participant might argue that the flavor language was arbitrary and capricious because the record reflected evidence that smokers needed flavors to switch and lacked evidence of flavors attracting new users or youth.³¹⁴ Mr. Shelanski explained that because the data and science on these issues was uncertain at the time, it would have been “fatally speculative” to include the flavor language in the rule.³¹⁵ Secretary Burwell, however, caveated that officials anticipated potential action on flavored e-cigarettes “once more data had been gathered that would more unambiguously support taking that action.”³¹⁶

IV. YOUTH E-CIGARETTE USAGE GREW DRAMATICALLY AFTER THE PUBLICATION OF THE FINAL DEEMING RULE

As noted above, the final deeming rule was published in May 2016.³¹⁷ Although officials defended the decision to remove the flavor language based on the lack of evidence on youth usage of e-cigarettes—particularly flavored e-cigarettes—available at the time,³¹⁸ in the months and years after the publication of the rule, youth e-cigarette use grew dramatically in the United States. As noted above, high school students’ use of e-cigarettes increased from 1.5 percent (220,000 students) in 2011 to 20.8 percent (3.05 million students) in 2018, and use among middle school students increased from 0.6 percent (60,000 students) in 2011 to 4.9 percent (570,000 students) in 2018.³¹⁹ By 2018, more than 3.6 million middle school and high school students used e-cigarettes—an increase of more than 1.5 million students from 2017.³²⁰ In 2019, 27.5 percent of high school students (4.1 million students) and 10.5 percent of middle school students (1.5 million students) reported using e-cigarettes within 30 days of being surveyed.³²¹

³¹² Zeller Interview (July 2, 2020). In addition, Mr. Zeller told the Subcommittee: “HHS and the White House had cleared the version of the final rule eliminating enforcement discretion for flavored products. Comm[unication]s materials had been drafted, a press event had been scheduled, and it was all to be announced in January 2016.” On the day of the scheduled event, “FDA [was] informed that everything was on hold while a cleared rule was reconsidered.” Mr. Zeller said that he had “never seen a rule get [to] the point of ‘rollout day’ only to be put on hold and then to be the object of major substantive changes.” Email from Mr. Zeller to the Subcommittee (Feb. 24, 2024).

³¹³ Burwell Statement (Aug. 3, 2020); Shelanski Interview (Apr. 9, 2020).

³¹⁴ Shelanski Interview (Apr. 9, 2020).

³¹⁵ *Id.* Mr. Zeller told Subcommittee staff that as CTP Director, he was not concerned about legal issues like the arbitrary and capricious challenge Mr. Shelanski described. Zeller Interview (July 2, 2020).

³¹⁶ Burwell Statement (Aug. 3, 2020).

³¹⁷ Deeming Rule, 81 Fed. Reg. 28,974.

³¹⁸ Shelanski Interview (Apr. 9, 2020).

³¹⁹ Cullen et al., *supra* note 75, at 1276.

³²⁰ *Id.*; RESULTS FROM 2018 NATIONAL YOUTH TOBACCO SURVEY, *supra* note 75. Between 2017 and 2018, current e-cigarette use among high school students increased 78 percent, from 11.7 percent to 20.8 percent (3.05 million students), and current use by middle school students increased 48 percent from 3.3 percent to 4.9 percent (570,000 students). Cullen et al., *supra* note 75, at 1276.

³²¹ 2019 Tobacco Product Use and Associated Factors, *supra* note 78.

The increase in youth usage is largely attributable to flavored products. According to the U.S. Surgeon General, between 2017 and 2018, flavored e-cigarette use by high school students rose from 60.9 percent to 67.8 percent, and menthol use increased from 42.3 percent to 51.2 percent.³²² Although the 2020 NYTS showed a decline in current high school and middle school e-cigarette use, “3.6 million U.S. youths still currently used e-cigarettes in 2020,” and of those, more than 80 percent reported using flavored e-cigarettes.³²³ The most recent 2023 NYTS also showed that 2.13 million students currently used e-cigarettes, and 89.4 percent used flavored e-cigarettes.³²⁴ As detailed in Part III below, the increase in youth usage and flavored products corresponded to the rise of JUUL as the largest player in the e-cigarette industry. In addition, Part V below describes Puff Bar’s rise to become the most popular e-cigarette brand among youth after JUUL’s flavored products were pulled from the U.S. market.

³²² U.S. FOOD & DRUG ADMIN., 2018 NYTS DATA: A STARTING RISE IN YOUTH E-CIGARETTE USE (2020); Cullen et al., *supra* note 75.

³²³ 2020 E-cigarette Use Among Middle and High School Students, *supra* note 80.

³²⁴ 2023 Tobacco Product Use Among U.S. Middle and High School Students, *supra* note 85, at 1173.

PART III: JUUL CAPTURED THE E-CIGARETTE MARKET AFTER 2016, USING FLAVORED PRODUCTS AND OTHER TECHNIQUES THAT APPEALED TO YOUTH AND YOUNG ADULTS

Between 2015 and 2018, sales of the JUUL vaping device grew dramatically in the United States, establishing JUUL as the clear leader in the e-cigarette market and leading to a \$38 billion valuation for the company in late 2018. At the same time, JUUL introduced thousands of youth to nicotine—at least partially reversing progress government officials and anti-smoking advocates achieved in the 1990s and 2000s. Although JUUL distinguished itself from traditional cigarette manufacturers, the company nevertheless followed a playbook similar to those that traditional tobacco companies had used: emphasizing non-traditional flavors, using a colorful, youthful, and “cool” marketing campaign, and engaging in “youth prevention” efforts that may have actually served to promote nicotine products among underage users.

In conversations with the Subcommittee, JUUL employees claimed not to have anticipated the impact of these factors on underage e-cigarette use. Yet, internal documents show the company recognized that its products, especially flavored products, appealed strongly to youth users. Despite this knowledge, the company took few efforts to curb sales of its products to youth.

I. COMPANY BACKGROUND

Adam Bowen and James Monsees, the co-founders of JUUL, met in a product design graduate program at Stanford University.³²⁵ The two bonded over their smoking habits and set out to develop an alternative to combustible cigarettes.³²⁶ As part of their graduate thesis, Mr. Bowen and Mr. Monsees designed a prototype of a nicotine vaping device, which they continued to develop after graduation in 2005.³²⁷ In 2007, Mr. Bowen and Mr. Monsees founded Ploom, Inc. (“Ploom”), and in 2010, the company introduced its first e-cigarette product—a butane-powered device known as the modelOne that “resembled a fountain pen” and vaporized tobacco pods.³²⁸ The product was “a dud,” selling only a few thousand units and leading Mr. Bowen and Mr. Monsees to develop alternative products.³²⁹

Given low sales of the modelOne, Ploom sought external investment—ultimately from Japan Tobacco International (“JTI”), which at the time was the fourth-largest tobacco company in the world and owned the Camel and Winston cigarette brands.³³⁰

³²⁵ Matt Richtel & Sheila Kaplan, *Did Juul Lure Teenagers and Get ‘Customers for Life’?*, N.Y. TIMES (Aug. 27, 2018), <https://www.nytimes.com/2018/08/27/science/juul-vaping-teen-marketing.html>.

³²⁶ *Id.*

³²⁷ *Id.*; Kevin Roose, *Juul’s Convenient Smoke Screen*, N.Y. TIMES (Jan. 11, 2019), <https://www.nytimes.com/2019/01/11/technology/juul-cigarettes-marketing.html>.

³²⁸ JLI-PSI-00450922; David Freedman, *How Do You Sell a Product When You Can’t Really Say What It Does?*, INC. MAGAZINE (May 2014), <https://www.inc.com/magazine/201405/david-freedman/james-monsees-ploom-ecigarette-company-marketing-dilemma.html>; Richtel & Kaplan, *supra* note 325.

³²⁹ Freedman, *supra* note 328.

³³⁰ *Id.*

With access to JTI’s scientists and marketing teams, in 2012, Ploom introduced the PAX, a device resembling an iPhone that vaporized loose leaf tobacco instead of pods.³³¹ “The device was a hit, receiving glowing praise from the press and tech blogs.”³³² In January 2015, however, the company sold Ploom naming rights and products to JTI and changed its name to Pax Labs, Inc. (“Pax Labs”) several months later.³³³

In June 2015, Pax Labs introduced the JUUL product—a thin device resembling a USB stick that vaporized nicotine from disposable pods.³³⁴ After a slow start in 2015, JUUL sales and revenue began to increase steadily following the passage of the deeming rule.³³⁵ For example, the number of JUUL devices sold per year jumped from 286,787 in 2016 to 2,285,342 in 2017, and the total number of JUUL pods sold increased from 10,540,640 to 74,176,048.³³⁶ JUUL reported selling 291,876,564 pods between January and August 2018.³³⁷ Gross sales revenues correspondingly increased from \$5,122,604 in 2015 to \$32,212,092 in 2016 and \$215,883,180 in 2017.³³⁸ Over this period, the term “Juuling” became a commonly used verb.³³⁹

Pax Labs spun off as a separate company in June 2017, and JUUL was established to sell the JUUL device and associated products.³⁴⁰ In addition, Pax Labs Chief Executive Officer (“CEO”) Tyler Goldman was also named CEO of JUUL.³⁴¹ JUUL developed its own marketing department in late 2017 and 2018.³⁴² When Mr. Goldman left the company in late 2017, he was replaced as CEO by Kevin Burns, who previously served as Chief Operating Officer of yogurt maker Chobani.³⁴³ In 2019, Mr. Burns was replaced by K.C. Crosthwaite, a chief growth officer at Altria Group, Inc. (“Altria”), who remains CEO today.³⁴⁴

In late 2018, Altria, the parent company of Philip Morris, paid approximately \$13 billion for a 35 percent stake in JUUL.³⁴⁵ Through this transaction, JUUL received

³³¹ *Id.*

³³² *Id.*

³³³ JLI-PSI-00450922.

³³⁴ *Id.*; David Pierce, *This Might Just Be the First Great E-Cig*, WIREd (Apr. 21, 2015), <https://www.wired.com/2015/04/pax-juul-ecig/>.

³³⁵ Richtel & Kaplan, *Did Juul Lure Teenagers*, *supra* note 325.

³³⁶ JLI-PSI-00450946.

³³⁷ *Id.*

³³⁸ JLI-PSI-00450947.

³³⁹ Richtel & Kaplan, *Did Juul Lure Teenagers*, *supra* note 325.

³⁴⁰ JLI-PSI-00450922.

³⁴¹ Ari Levy, *E-Cigarette Maker Juul is Raising \$150 Million After Spinning Out of Vaping Company*, CNBC (Dec. 19, 2017), <https://www.cnbc.com/2017/12/19/juul-labs-raising-150-million-in-debt-after-spinning-out-of-pax.html>.

³⁴² JLI-PSI-00450925.

³⁴³ Levy, *supra* note 341.

³⁴⁴ Chris Isidore, *Juul CEO Is Out, and It Stops All Advertising as Vaping Crisis Escalates*, CNN (Sept. 25, 2019), <https://www.cnn.com/2019/09/25/business/juul-ceo-resigns/index.html>; JUUL Labs, Inc., *Our Team*, <https://www.juulabs.com/about/company/our-team/> (last visited Jan. 24, 2023).

³⁴⁵ Sheila Kaplan & Matt Richtel, *Juul Closes Deal with Tobacco Giant Altria*, N.Y. TIMES (Dec. 20, 2018), <https://www.nytimes.com/2018/12/20/health/juul-reaches-deal-with-tobacco-giant-altria.html>. In October 2020, JUUL dropped its valuation to approximately \$10 billion—a contrast to its valuation of \$38

access to Altria’s marketing and distribution system, which included significant shelf space in convenience stores. Altria also provided perspective to JUUL based on “years of experience and literally hundreds if not thousands of interactions with the F.D.A.”³⁴⁶ In 2020, the Federal Trade Commission (“FTC”) filed an administrative complaint alleging that Altria’s investment in JUUL eliminated competition and violated antitrust law.³⁴⁷ In 2022, an FTC Administrative Law Judge (“ALJ”) dismissed the Commission’s antitrust charges and ruled for the companies.³⁴⁸ The FTC had to decide whether to appeal or accept that decision and dismiss the case.³⁴⁹ On March 3, 2023, Altria relinquished its 35 percent ownership interest in JUUL and terminated its 2018 agreement with the company.³⁵⁰ Subsequently, Altria asked the FTC to dismiss the agency’s case.³⁵¹ On June 30, 2023, the FTC vacated the ALJ’s initial decision and the agency dismissed the complaint.³⁵²

II. JUUL MARKETED AND PROFITED FROM A PORTFOLIO OF NON-TRADITIONAL FLAVORS

Since its 2015 launch, JUUL has marketed a portfolio of traditional flavored products familiar to the tobacco industry—Tobacco and Menthol—and until 2019, it also marketed non-traditional flavors, including Fruit Medley, Mango, Cucumber, and Mint.³⁵³ JUUL also released special edition flavors—“Coco Miint” during the holidays, for

billion in 2018 when Altria took a stake in the company. Jennifer Maloney, *Juul Cuts Valuation to \$10 Billion*, WALL ST. J. (Oct. 29, 2020), <https://www.wsj.com/articles/juul-cuts-valuation-to-10-billion-11603994473>.

³⁴⁶ Kaplan & Richtel, *Juul Closes Deal*, *supra* note 345.

³⁴⁷ Complaint, Altria Group, Inc., and JUUL Labs, Inc., FTC No. 9393 (Apr. 1, 2020), https://www.ftc.gov/system/files/documents/cases/d09393_administrative_part_iii_complaint_public_version.pdf.

³⁴⁸ Initial Decision, Altria Group, Inc., and JUUL Labs, Inc., FTC No. 9393 (Feb. 23, 2022), https://www.ftc.gov/system/files/ftc_gov/pdf/d09393altriainitialdecisionpublic.pdf.

³⁴⁹ Order Denying Stay and Extending Decision Deadline for Commission Ruling, Altria Group, Inc., and JUUL Labs, Inc., FTC No. 9393 (Mar. 30, 2023), https://www.ftc.gov/system/files/ftc_gov/pdf/D09393-Commission-Order-Extending-Decision-Deadline%28Signed%29.pdf.

³⁵⁰ Respondents’ Motion to Take Official Notice and to Dismiss This Litigation as Moot, or in the Alternative, to Stay the Litigation, Altria Group, Inc., and JUUL Labs, Inc., FTC No. 9393 (Mar. 6, 2023), https://www.ftc.gov/system/files/ftc_gov/pdf/607120_d09393-respondents_motion_to_take_official_notice_and_to_dismiss_this_litigation_as_moot_or_in_the_alternative_to_stay_the_litigation.pdf.

³⁵¹ *Id.*

³⁵² Press Release, U.S. Fed. Trade Comm’n, Commission Order Vacates ALJ Initial Decision and Dismisses Complaint in Case Against Altria and Juul (July 3, 2023), <https://www.ftc.gov/news-events/news/press-releases/2023/07/commission-order-vacates-alj-initial-decision-dismisses-complaint-case-against-altria-juul>.

³⁵³ Allison Aubrey, *JUUL Suspends Sales of Flavored Vapes and Signs Settlement to Stop Marketing to Youth*, NPR (Oct. 17, 2019), <https://www.npr.org/sections/health-shots/2019/10/17/771098368/juul-suspends-sales-of-flavored-vapes-and-signs-settlement-to-stop-marketing-to>; Angelica Pebbles, *JUUL Halts Sales of its Popular Mint Flavor*, CNBC (Nov. 7, 2019), <https://www.cnbc.com/2019/11/07/juul-halts-sales-of-its-popular-mint-flavor.html>. JUUL’s original portfolio of flavors included “Tabaac,” “Miint,” “Fruut,” and “Bruulé”. See JLI-PSI-00029635; Ryan Lawler, *Vaporization Startup Pax Labs Introduces Juul, Its Next-Gen E-Cigarette*, TECH CRUNCH (Apr. 21, 2015), <https://techcrunch.com/2015/04/21/pax-juul/>.

example³⁵⁴—and worked with partner companies to develop JUUL-compatible flavors, particularly sweet and fruity varieties, to complement the company’s existing flavor portfolio.³⁵⁵ Flavored offerings from JUUL mirrored similar products tobacco companies had developed previously to appeal to younger or first-time users. The sale of these non-traditional flavors played a central role in JUUL’s rise in the e-cigarette market, as the company’s revenue growth corresponded with the increase in sales of non-traditional pods.³⁵⁶ In fact, by 2018, the sale of non-traditional flavored products was so central to the company that a JUUL consultant reportedly equated any move by the company to stop selling non-traditional flavored products with JUUL ending all product sales.³⁵⁷

A. Non-Traditional Flavored Pods Were Central to JUUL’s Rise in the E-cigarette Market

Despite its high-profile launch campaign discussed below, JUUL sales remained relatively low in 2015 and 2016, with the company capturing less than a three percent share of the e-cigarette market during this period.³⁵⁸ Internal financial documents show that JUUL revenue tracked well below company targets in the months after launch.³⁵⁹ Tobacco and Mint were the best-selling flavors during this time, with other non-traditional flavors “each accounting for [less than 15 percent] of total volume.”³⁶⁰

In mid-2017, however, JUUL’s market share began to increase rapidly.³⁶¹ By the end of 2017, it had captured more than 50 percent of the e-cigarette market,³⁶² and

³⁵⁴ See JUUL Labs (@JUULvapor), TWITTER (June 20, 2016 11:54 AM), <https://twitter.com/juulvapor/status/744921384376164352?lang=en> (“Coco Miint was a limited release for the holidays. It’s no longer available, but keep an eye on us for updates in the future!”).

³⁵⁵ See JLI-PSI-00127755 (discussing new flavors to be added, including “+17 pod flavors in 2 packs & 4 packs” and “+29 partner pod flavors with 7 major juice brands”); JLI-PSI-00126152–53 (describing as part of the flavor portfolio “flavors not widely available,” including “Mixed Berry,” “Apple Cran,” “Apple Tart,” “Coco Mint,” “Cookies & Cream,” and “Chestnut Croissant,” as well as “private blend flavors not widely available,” including “Banana Creme,” “Grandmaster,” “Grapevine,” “Apple Cinnamon,” “Cinnamon Beignet,” “Peppermint,” “Kiwi,” “Orange,” “Citrus Medley,” and “Peach Crème”).

³⁵⁶ See *infra* Part III, Section II.A.

³⁵⁷ See *id.*

³⁵⁸ See Interview with Chelsea Kania, former Exec. Dir. Brand & Prod. Mktg, JUUL Labs, Inc. (Nov. 15, 2019) [hereinafter Kania Interview (Nov. 15, 2019)].

³⁵⁹ See JLI-PSI-00149876 (showing June 2015 sales of approximately \$120,000, well below the target of \$460,000); JLI-PSI-00030527 (showing sales in November 2015 that were below target).

³⁶⁰ JLI-PSI-00149875. See also JLI-PSI-00149878; JLI-PSI-00030530–31; JLI-PSI-00030488.

³⁶¹ Kania Interview (Nov. 15, 2019).

³⁶² See JLI-PSI-00126169; JLI-PSI-00349518.

JUUL reported over \$1 billion in revenue in 2018.³⁶³ JUUL had captured over 70 percent of the U.S. e-cigarette market as of mid-2019.³⁶⁴

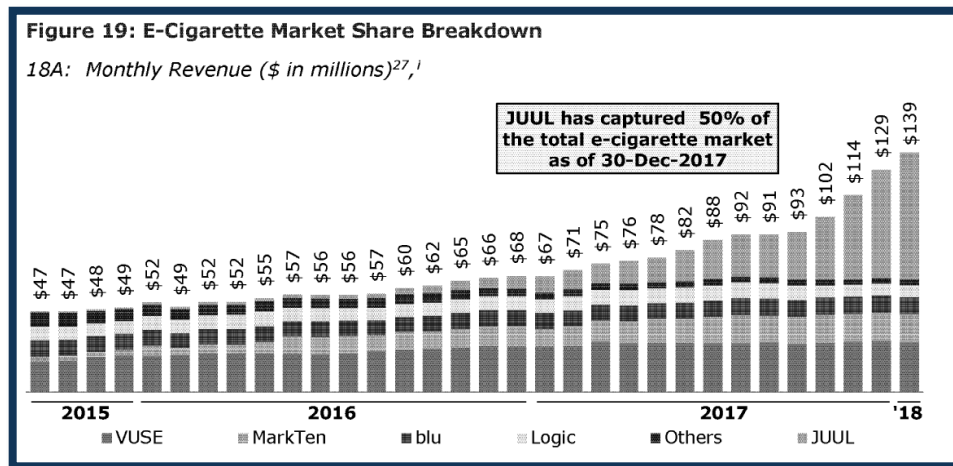


Figure 3: JUUL Revenue Compared to Competitors (2015 - Early 2018)³⁶⁵

While the company was “very surprised” by the sudden increase in revenue and market share, Chelsea Kania, who served as JUUL brand manager and later became Executive Director of Brand and Product Marketing, explained to Subcommittee staff that JUUL never “had a great handle on” the underlying causes of this growth.³⁶⁶ One significant factor, however, appears to have been the uptick in sales of non-traditional flavored JUUL pods after finalization of the deeming rule and the federal government’s decision not to remove flavored products from the market. In fact, in contrast to the “addressable market” of adult cigarette smokers, who had a “stronger affinity for tobacco flavors,” a 2017 company analysis of online sales data found that most JUUL users preferred fruit and mint/menthol flavors.³⁶⁷

By the end of 2017, Mango and Mint pods accounted for the majority of JUUL sales—approximately 70 percent of both retail and e-commerce sales.³⁶⁸ The share attributable to Tobacco pods, in contrast, fell to only around 10 percent of retail sales

³⁶³ See Altria Group, Altria Group Q4 2018 Earnings Conference Call Transcript (Feb. 1, 2019), <https://www.fool.com/earnings/call-transcripts/2019/02/01/altria-group-q4-2018-earnings-conference-call-t.aspx>. See also Dawn Kawamoto, *Juul Labs Revenue Soars to More Than \$1 Billion in 2018*, SAN FRANCISCO BUS. TIMES (Feb. 1, 2019), <https://www.bizjournals.com/sanfrancisco/news/2019/02/01/juul-labs-revenue-soars-to-more-than-1-billion.html>; Uday Kumar, *Altria Says Juul Sales Skyrocket to \$1 Billion in 2018*, REUTERS (Jan. 31, 2019), <https://www.reuters.com/article/us-altria-group-juul/altria-says-juul-sales-skyrocket-to-1-billion-in-2018-idUSKCN1PP1YJ>.

³⁶⁴ Jennifer Maloney, *Juul Explores Opening Its Own E-Cigarette Stores*, WALL ST. J. (May 30, 2019), www.wsj.com/articles/juul-explores-opening-its-own-e-cigarette-stores-in-u-s-11559235262.

³⁶⁵ See JLI-PSI-00126169.

³⁶⁶ Kania Interview (Nov. 15, 2019).

³⁶⁷ JLI-PSI-00322007; Interview with Steve Hong, then-Senior Dir. Consumer Insights, JUUL Labs, Inc. (Nov. 20, 2019) [hereinafter Hong Interview (Nov. 20, 2019)].

³⁶⁸ See JLI-PSI-00069833. See also JLI-PSI-00041607 (“Fascinating to see the flavor splits – mango overtaking mint! . . . Cool Cucumber is still holding pretty well . . .”).

and 18 percent of online sales.³⁶⁹ Similar statistics compiled internally in April 2018 revealed the degree to which JUUL, in contrast to its competitors, relied on certain non-traditional flavored products to drive sales:

	Flavor Categories by Dollar Sales		Flavor Categories by Unit Sales	
	Competitor	JUUL	Competitor	JUUL
Dessert	2%	6%	3%	7%
Fruit	13%	28%	12%	30%
Menthol / Mint	35%	33%	37%	35%
Other	1%	1%	1%	1%
Tobacco	43%	15%	44%	21%
Unidentifiable	6%	16%	3%	6%

Figure 4: Flavor Categories at JUUL and Competitors by Percentage of Dollar and Unit Sales³⁷⁰

While JUUL’s percentage of sales from Menthol and Mint pods was comparable to other manufacturers, its percentages of sales from dessert-flavored and fruit-flavored pods were more than twice as high. By contrast, JUUL’s percentage of sales from Tobacco pods was less than half the share attributable to similar products among its competitors. Figures from later in 2018 also reflected the decreasing proportion of sales from Tobacco pods as compared to sales of non-traditional flavored pods, which continued to increase.³⁷¹ Flavored products were seen as so central to JUUL during this period that, according to notes from an internal JUUL meeting, Iowa Attorney General Tom Miller—whom the company retained as a consultant to advise on youth prevention efforts—allegedly stated that if JUUL stopped selling non-traditional flavors, this “would [be] the same as stop selling [sic] the product.”³⁷²

After JUUL stopped selling pods in flavors other than Tobacco, Mint, and Menthol in mid-2019, Mint sales skyrocketed. At a February 2020 hearing before the Subcommittee on Oversight and Investigations of the House Committee on Energy and Commerce, current JUUL CEO K.C. Crosthwaite testified that Mint pods accounted for 70 percent of company revenue as of late 2019.³⁷³ JUUL subsequently ended sales of Mint pods due to their popularity among youth.³⁷⁴

³⁶⁹ See JLI-PSI-00069833.

³⁷⁰ JLI-PSI-00340748.

³⁷¹ See JLI-PSI-00028598.

³⁷² JLI-PSI-00155995.

³⁷³ *Vaping in America: E-Cigarette Manufacturers’ Impact on Public Health: Hearing Before the Subcomm. on Oversight and Investigations of the H. Comm. on Energy and Commerce, 116th Cong. (2020)* (statement of K.C. Crosthwaite, CEO, JUUL) [hereinafter *Vaping in America*].

³⁷⁴ *Id.*

B. JUUL Viewed Flavors as Important Because They Encouraged Customer Use and Cemented Loyalty

JUUL viewed flavors as central to its business model because of the role flavored products play in attracting and retaining e-cigarette customers.³⁷⁵ A 2013 report Steve Hong, the former Senior Director of Consumer Insights, authored prior to joining JUUL, for example, concluded that “[f]lavor is the most important consideration in initial purchase” of e-cigarettes.³⁷⁶ Similarly, the CDC has stated, “existing science demonstrates that flavors play a key part in e-cigarette initiation.”³⁷⁷ As Mr. Hong explained to the Subcommittee, flavors can compensate for unsatisfying aspects of e-cigarettes as a user attempts to replace traditional cigarettes.³⁷⁸

JUUL also knew that flavors played an equally important role in retaining existing customers, a connection that multiple marketing consultants underscored to the company.³⁷⁹ In 2017, for example, JUUL commissioned a third-party vendor to study the needs of traditional cigarette smokers and vapers.³⁸⁰ The vendor explained that flavors help “create rituals” and encourage users to “settle into the [JUUL] system.”³⁸¹ Moreover, because flavors can create a “positive state of mind” and provide a “moment to relax,” users associate flavors with pleasure—which “can tie [them] into Juul use.”³⁸² Flavors, in other words, serve as a “key transition” from initial purchase to regular JUUL use.³⁸³ Similarly, an internal report from April 2018 suggested that JUUL could “use [its] flavors strategically to mitigate churn and establish loyalty amongst [its] design target” and listed “having [one’s] favorite flavors” as one of the “most important attributes in predicting satisfaction with JUUL.”³⁸⁴

Given the significant role of flavors in e-cigarette user satisfaction and loyalty, employees and consultants consistently recommended that JUUL expand its flavor portfolio. One vendor, for example, noted that the company had a “limited number of options and less flavor than the competition” and recommended that it experiment with “fuller flavors,” “create more premium, single note flavors,” and consider seasonal or

³⁷⁵ See, e.g., JLI-PSI-00391958–59 (“Based on our initial focus group testing on JUUL, we’ve identified that flavor quality and flavor variety are among the most important factors for current and prospective vape consumers. . . . Based on this information, we recommend a consistent flavor introduction schedule to appeal to current and prospective consumers. This strategy will allow us to continue to build momentum in the marketplace and generate excitement around the JUUL brand.”).

³⁷⁶ See JLI-PSI-00401251.

³⁷⁷ Briefing with U.S. Ctrs. for Disease Control & Prevention (Apr. 3, 2019).

³⁷⁸ See Hong Interview (Nov. 20, 2019).

³⁷⁹ See JLI-PSI-00401256, JLI-PSI-00401272.

³⁸⁰ JLI-PSI-00405228.

³⁸¹ See *id.*; Hong Interview (Nov. 20, 2019).

³⁸² See JLI-PSI-00405228.

³⁸³ *Id.*

³⁸⁴ JLI-PSI-00116157. Mr. Hong defined “churn” as when a consumer tries a product but does not continue to use it after a period of time. Hong Interview (Nov. 20, 2019). JUUL employees informed the Subcommittee that the “design target” was a set of personas the company developed with McKinsey & Company. See Hong Interview (Nov. 20, 2019); Kania Interview (Nov. 15, 2019). The personas described in depth were aged 28 and 40. See JLI-PSI-00116157.

limited flavor editions.³⁸⁵ Doing so, the vendor advised, would “make flavor[s] even more enticing, encouraging users to sample new experiences.”³⁸⁶ Similarly, a consultant JUUL retained in 2018 stressed that “flavors are the highest motivators for consumption and for social interaction.”³⁸⁷ She advised the company to “[l]everage flavor favorites and add complementary new flavors for variety and novelty.”³⁸⁸

Inside the company, a 2016 marketing document proposed introducing new flavors before the end of the year to provide a “stronger proposition” for certain consumers to try JUUL.³⁸⁹ The same document suggested that JUUL’s inability to capture a larger market share up to that point was partly because its non-traditional flavor portfolio lagged behind that of its competitors.³⁹⁰ A 2018 internal report, tracking awareness of the JUUL brand among consumers, speculated that “[b]y offering a wider range of flavors, [JUUL] may reduce the number of brand switch decisions among [its] promiscuous consumers.”³⁹¹ A commercial planning document from the same month also described releasing new flavors as “critical to maintaining strong user experience in [the] near term.”³⁹²

Because JUUL recognized the importance of flavors to its business model, it conducted annual evaluations of its existing portfolio and tested new flavors. JUUL expected these annual flavor tests “to add incremental revenue to the business, gain consumer data and allow [it] more opportunities to engage with [its] customers.”³⁹³ To assist in identifying flavors to introduce, JUUL hired a third-party vendor to test which varieties—JUUL-branded as well as partner flavors—had “broad appeal.”³⁹⁴ Tested flavors included “Headbangin Boogie,” “Wonderworm,” “Bird Brains,” “Mr. Fritter,” “Sugar Drizzle,” and “Unicorn Milk,” along with “Cool Cucumber,” “Cool Mint,” “Mango,” and “Smooth Menthol.”³⁹⁵

³⁸⁵ See JLI-PSI-00405228.

³⁸⁶ See *id.*

³⁸⁷ See JLI-PSI-00335702.

³⁸⁸ See JLI-PSI-00335703.

³⁸⁹ See JLI-PSI-00391959.

³⁹⁰ See *id.* (“Furthermore, Industry trends are showing that 84% of vape brands offer fruit flavors, 80% offer dessert flavors, 77% offer alcohol/drink flavors, and 25% offer snack/meal flavors. By expanding our flavor portfolio into these categories, we gain better positioning in the market to appeal to a wider range of consumers.”).

³⁹¹ JLI-PSI-00116157.

³⁹² See JLI-PSI-00233342.

³⁹³ JLI-PSI-00391957.

³⁹⁴ See JLI-PSI-00324776; JLI-PSI-00324774 (“[W]e’ll likely launch >10 flavors next year, but before we spin our wheels selecting the best do you have a timeline for [toxicology] analysis for our flavors & the partner flavors?”).

³⁹⁵ See JLI-PSI-00324776.

C. JUUL Focused on Non-Traditional Flavors Despite Knowing They Appealed to Youth and Young Adults

JUUL focused on non-traditional flavors despite its awareness that these flavors appealed to younger populations.³⁹⁶ Internal documents reveal that certain JUUL executives and employees viewed flavors as so central to its business that they would not “get rid of flavors” without strong data demonstrating a clear link between flavors and youth usage.³⁹⁷ In taking this position, despite knowing the strong appeal of certain non-traditional flavored products to younger adults and youth, JUUL contributed to rising rates of nicotine use by these populations. As a recent study explained, “[y]outh e-cigarette users commonly cited flavors as a top reason for e-cigarette initiation, second only to use by a family member or friend.”³⁹⁸ A March 2019 FDA survey similarly found that 97 percent of the participating youth e-cigarette users reported using flavored products within a month of the survey.³⁹⁹

1. JUUL Recognized That Non-Traditional Flavors Appealed to Younger Populations

Numerous studies document the connection between youth tobacco use and flavored products. As early as 2012, the U.S. Surgeon General drew a connection between the rise in smokeless tobacco use among younger adults and “the marketing of flavored tobacco products that, like cigarettes, might be expected to be attractive to youth.”⁴⁰⁰ In 2016, the U.S. Surgeon General found that flavors were among the most commonly-cited reasons by youth and young adults for using e-cigarettes.⁴⁰¹ The 2019 NYTS found that nearly seven in ten tobacco-using middle and high school students used flavored products; among students who had ever tried e-cigarettes, nearly one in four cited “flavors, such as mint, candy, fruit, or chocolate,” as the reason for their use.⁴⁰² In 2020 and 2021, approximately eight in ten students who used e-cigarettes reported using flavored e-cigarettes.⁴⁰³ In the most recent NYTS, 89.4 percent of current student users used flavored e-cigarettes, and among those students, 63.4 percent used fruit flavors and 35 percent used candy flavors.⁴⁰⁴

³⁹⁶ See *infra* Part III, Section II.C.1.

³⁹⁷ See JLI-PSI-00155978.

³⁹⁸ Donna Vallone et al., *Electronic Cigarette and Juul Use Among Adolescents and Young Adults*, 174 JAMA PEDIATRICS 277, 283 (2020) (citing James Tsai et al., *Reasons for Electronic Cigarette Use Among Middle and High School Students—National Youth Tobacco Survey, United States, 2016*, 67 MORBIDITY & MORTALITY WKLY. REP. 196 (2018)).

³⁹⁹ U.S. FOOD & DRUG ADMIN., MODIFICATIONS TO COMPLIANCE POLICY FOR CERTAIN DEEMED TOBACCO PRODUCTS (2019).

⁴⁰⁰ 2012 SURGEON GEN. REP., *supra* note 11.

⁴⁰¹ 2016 SURGEON GEN. REP., *supra* note 51.

⁴⁰² Press Release, U.S. Ctrs. for Disease Control & Prevention, 6.2 Million Middle and High School Students Used Tobacco Products in 2019 (Dec. 5, 2019), <https://archive.cdc.gov/#/details?url=https://www.cdc.gov/media/releases/2019/1205-nyts-2019.html>.

⁴⁰³ 2020 *E-cigarette Use Among Middle and High School Students*, *supra* note 80; 2021 *E-cigarette Use Among Middle and High School Students*, *supra* note 82.

⁴⁰⁴ 2023 *Tobacco Product Use Among U.S. Middle and High School Students*, *supra* note 85, at 1173.

Mr. Hong informed the Subcommittee that it is commonly understood that younger adult smokers “tend to express more interest” in non-traditional flavors.⁴⁰⁵ In fact, JUUL received specific evidence that its non-traditional flavored products appealed to younger populations. By 2017 and throughout 2018, JUUL regularly received complaints from concerned parents and third parties about the company’s non-traditional flavors attracting youth users.⁴⁰⁶ In fact, a member of JUUL’s Education & Youth Prevention department noted that “[t]he same flavors that are popular with adult smokers . . . seem to be just as popular among youth who may initially be unaware of the product’s nicotine content and its intended purpose to displace combustible cigarettes.”⁴⁰⁷ A May 2018 survey by the consulting firm McKinsey & Company (“McKinsey”), which JUUL executives reviewed, showed that individuals aged 13 to 20 preferred fruit flavors, with mango being among the highest-rated flavors.⁴⁰⁸ At the same time, this demographic showed a strong dislike—far more than other age groups—for the more traditional “Virginia Tobacco” and “Menthe” flavors.⁴⁰⁹ When asked about this study, Mr. Hong indicated that many within the company, including then-CEO Kevin Burns, dismissed the results because of what they viewed as McKinsey’s “questionable methodology.”⁴¹⁰

In August 2018, JUUL convened a “Youth Advisory Council”—consisting of approximately one dozen individuals aged 21 and older—“to get a perspective from young adults on how to combat the use of JUUL amongst underage kids.”⁴¹¹ According to Julie Henderson, the former Director of Education & Youth Prevention, the participants in this council served as proxies for underage users that might be attracted to JUUL.⁴¹² Council participants highlighted that JUUL products appealed to youth in particular because its “flavors taste[d] good.”⁴¹³ One participant noted, “[f]lavors, such as fruit medley and mint, as well as the sleekness of the product, are attractive to kids.”⁴¹⁴ Ms. Henderson told Subcommittee staff that these findings were shared with top JUUL executives, including then-Chief Administrative Officer Ashley Gould, but Ms. Henderson was not aware of any actions JUUL executives took in response.⁴¹⁵

⁴⁰⁵ Hong Interview (Nov. 20, 2019).

⁴⁰⁶ See, e.g., JLI-PSI-00030942.

⁴⁰⁷ JLI-PSI-00154737.

⁴⁰⁸ See JLI-PSI-00333207.

⁴⁰⁹ See *id.*

⁴¹⁰ Hong Interview (Nov. 20, 2019).

⁴¹¹ Interview with Julie Henderson, then-Dir. Youth Prevention & Educ., JUUL Labs, Inc. (Nov. 22, 2019) [hereinafter Henderson Interview (Nov. 22, 2019)]; JLI-PSI-00157771.

⁴¹² Henderson Interview (Nov. 22, 2019). Ms. Henderson stated that the company used proxies because it would not survey individuals under the age of 18. *Id.*

⁴¹³ JLI-PSI-00157771; Andrea Villanti et al., *Flavored Tobacco Product Use Among U.S. Young Adults*, 44 AM. J. PREVENTATIVE MED. 388 (2013).

⁴¹⁴ JLI-PSI-00157771; Villanti et al., *supra* note 413.

⁴¹⁵ Henderson Interview (Nov. 22, 2019). Ms. Henderson explained that because the survey occurred around the time youth prevention efforts at the company were ending, JUUL executives likely saw no purpose in using the information. Ms. Henderson personally viewed flavors as “more of a plus” in terms of youth appeal, but she thought youth were more attracted to the rebelliousness of JUUL—being able to do “tricks” and use the device in front of adults without being caught, for example. See *id.*; JLI-PSI-00148821.

JUUL also failed to act on recommendations from consultants hired to provide guidance on its youth prevention efforts, who specifically advised the company to remove certain non-traditional flavors from the market.⁴¹⁶ Although JUUL considered initiating a study to analyze whether its flavors appealed to youth, the company ultimately scrapped the project due to fear of a public backlash on the “optics” of such an effort.⁴¹⁷

At the same time, JUUL employees clearly recognized the public relations dilemma that flavors presented for the company. In a July 2017 exchange with JUUL’s external public relations firm, Ms. Kania conveyed a potential “worst case” scenario that the public would perceive JUUL as marketing to youth through its portfolio of non-traditional flavors.⁴¹⁸ As the company faced growing public scrutiny, JUUL’s then-Chief Sales Officer outlined the same concern to various marketing employees:

We need to put some thinking towards how we present flavors in the market. The media is using crème brulee, fruit medley, and ‘cool’ mint/cucumber as talking points that we are intentionally trying to appeal to a younger audience. Of course it’s not true, but we need to come up with a better answer quickly.⁴¹⁹

JUUL did not take action on its non-traditional flavored products until 2018 and 2019, first shortening the names of flavors—from “Cool Mint” to “Mint,” for example—and subsequently suspending retail and online sales of non-traditional flavored pods.

2. Despite Emphasizing the Importance of Flavors to Adults Switching from Cigarettes, JUUL Could Not Articulate the Role of Flavors in the Transition

In response to criticism concerning its non-traditional flavors and their appeal to youth, JUUL has consistently cited the important role of flavors in helping adult smokers transition away from combustible cigarettes.⁴²⁰ For example, in responding to emails from concerned parents and third parties about the role of flavors and the youth vaping

⁴¹⁶ See, e.g., JLI-PSI-00159972–73 (recommending rotating out or renaming crème brulee); JLI-PSI-00161621 (“Kill Fruity Flavours: Replace with Adult Flavours”).

⁴¹⁷ See JLI-PSI-00426323; JLI-PSI-00353250; Hong Interview (Nov. 20, 2019); Henderson Interview (Nov. 22, 2019). Ms. Henderson stated that she planned to research which flavors might appeal to youth specifically. She also noted that JUUL recognized the need to know what products youth used, but no one at the company felt comfortable running such a study. Henderson Interview (Nov. 22, 2019).

⁴¹⁸ JLI-PSI-00286214; Kania Interview (Nov. 15, 2019).

⁴¹⁹ JLI-PSI-00397750.

⁴²⁰ See, e.g., JLI-PSI-00144656; JLI-PSI-00284075 (“Better flavor and flavor variety is one of the primary reasons that adult smokers try vaping. . . . So flavored vape products serve as both an incentive to switch and [a] disincentive to go back to smoking.”). Recent studies have undercut the argument that flavors are central to helping smokers stop using traditional cigarettes. According to an article in the *Journal of the American Medical Association Pediatrics*, relatively few adults used JUUL to quit smoking traditional cigarettes, and “[a]mong those aged 18 to 24 years, only 1 in 5 JUUL users reported trying the product to quit cigarette smoking.” Vallone et al., *supra* note 398.

epidemic, JUUL employees explained that the company’s flavors, “which [the public] believe[s] are aimed at a youth demographic, play an important role in helping adult smokers permanently switch from cigarettes to JUUL without dual usage.”⁴²¹ The company based these claims on anecdotal evidence employees had collected.⁴²² A JUUL report from April 2018 also found that consumers of non-traditional flavors, JUUL users of non-traditional flavors, and consumers who preferred non-traditional flavors all had higher “switch rates” than consumers who used or preferred traditional flavors.⁴²³ The analysis found, for example, that among consumers who preferred non-traditional flavors and who no longer smoked cigarettes, 42 percent preferred fruit flavors and only 27 percent preferred tobacco flavors.⁴²⁴

JUUL, however, appears not to have fully understood how or why flavors helped adult smokers stop using traditional cigarettes.⁴²⁵ In a September 2017 message, JUUL noted, for example, that its “data show that flavors do play an important role in helping adult smokers permanently switch from cigarettes to JUUL without dual useage [sic]. At this point we [do not] fully understand the reasons why.”⁴²⁶ It appears JUUL also lacked sufficient data related to this issue as of April 2018, when Mr. Burns wrote that “[t]he need to have data and survey info especially around switching rates is even more critical now.”⁴²⁷ Mr. Hong informed the Subcommittee that the Consumer Insights team, which was responsible for understanding how JUUL could “better serve the needs of adult smokers,” was never tasked with assessing the role flavors played in helping smokers switch from traditional cigarettes.⁴²⁸

III. JUUL USED OTHER MARKETING TECHNIQUES THAT ATTRACTED YOUTH

In addition to profiting from non-traditional flavors, JUUL utilized other marketing techniques that appealed to younger populations. JUUL designed its launch campaign—the “Vaporized” campaign—to be “colorful, approachable, dynamic and fun,” and included a mix of traditional marketing techniques and engagement with social media and online “influencers.” Although the company formally targeted individuals aged 25 to 34, the campaign resonated strongly with users well below this range. Further, JUUL utilized and greatly benefited from social media activity, with its initial investments in this area leading to vast amounts of user-generated viral content that continues to flourish online.

⁴²¹ See, e.g., JLI-PSI-00003957.

⁴²² See, e.g., *id.* (“With regard to our flavorings, from our user testimonials, smokers who have switched often report getting flavor fatigue”); JLI-PSI-00004625 (“Regarding our flavors, we have a large number of testimonials and anecdotal evidence regarding adult use of these flavors.”); JLI-PSI-00006788; Kania Interview (Nov. 15, 2019); Henderson Interview (Nov. 22, 2019).

⁴²³ JLI-PSI-00413859–61.

⁴²⁴ JLI-PSI-00413861.

⁴²⁵ See, e.g., JLI-PSI-00144656; JLI-PSI-00004625 (“[W]e are currently conducting our own scientific research to better understand the exact impact and drivers of flavors on a smoker’s switching behavior and will be working with the FDA as it too works through the data on flavors.”); JLI-PSI-00006788.

⁴²⁶ JLI-PSI-00144656.

⁴²⁷ JLI-PSI-00125889.

⁴²⁸ See Hong Interview (Nov. 20, 2019); JLI-PSI-00125889–90.

A. The Vaporized Launch Campaign

In June 2015, JUUL (then Pax Labs)⁴²⁹ launched its e-cigarette product with a campaign called “Vaporized,” which portrayed the JUUL brand as “colorful, approachable, dynamic and fun.”⁴³⁰ With the purported aim of reaching individuals aged 25 to 34, the resulting campaign featured a mix of “traditional, digital, experiential and influencer marketing.”⁴³¹

1. Target Demographic, Goals, and Inspiration

Prior to launching its product, JUUL sought to identify its target market opportunities.⁴³² The company retained Tragon Corporation (“Tragon”) to conduct an online survey to understand the e-cigarette market and the potential consumer base.⁴³³ The survey was open to individuals aged 18 to 55; based on the results, Tragon concluded that consumers between the ages of 26 and 35 were most likely to purchase the JUUL product.⁴³⁴

With this target demographic in mind, JUUL engaged Cult Collective to develop “the tone, look, and feel surrounding the launch of JUUL.”⁴³⁵ As an internal “campaign overview” explained, the goal of the campaign was to show “that the product is cool, and to remove the stigma of e-smoking because it is the better alternative to traditional cigarettes and other lame e-cigs – you can go out and be proud of JUUL.”⁴³⁶ JUUL pushed this branding in its media messaging and marketing, using phrases including, “[f]inally a cool, stylish ecigarette,” “JUUL is elegant and cool,” and “JUUL single-handedly made e-cigs cool.”⁴³⁷ In another example, JUUL explained in a response to a questionnaire about the brand: “The JUUL brand is colorful, approachable, dynamic and fun. Finally a cool, stylish ecigarette. Every other e-cigarette is douche-y. Finally, there’s JUUL. JUUL single-handedly made e-cigs cool. Light years ahead of everything else, nothing else is worth considering.”⁴³⁸

Ms. Kania, who served as JUUL brand manager at the time of the Vaporized campaign, informed the Subcommittee that the company and Cult Collective drew

⁴²⁹ See *supra* Part III, Section I. While the company JUUL was not established until June 2017, this report uses JUUL for ease of reference.

⁴³⁰ JLI-PSI-00029687.

⁴³¹ Kania Interview (Nov. 15, 2019); JLI-PSI-00034189.

⁴³² JLI-PSI-00125037.

⁴³³ *Id.*

⁴³⁴ *Id.*

⁴³⁵ JLI-PSI-00450922. According to JUUL’s responses to interrogatories from the Federal Trade Commission, “JUUL Labs . . . appointed advertising agency Cult Collective Ltd . . . as a creative consultant to provide branding advice in connection with the launch campaign for the JUUL products. Cult Collective was first engaged in July 2015 under a three-month contract, and thereafter served as the Company’s agency of record for the duration of 2015. Cult Collective was responsible for developing the tone, look, and feel surrounding the launch of JUUL.” JLI-PSI-00450922.

⁴³⁶ JLI-PSI-00034189.

⁴³⁷ JLI-PSI-00132331.

⁴³⁸ JLI-PSI-00035657.

inspiration for the Vaporized campaign from other technology companies, as well as from Pax Lab's experience with its product launches.⁴³⁹ According to Ms. Kania, the company did not review tobacco industry marketing campaigns and instead focused on being new, innovative, and different.⁴⁴⁰ Others, however, have alleged that the company's co-founders drew inspiration from the tobacco industry. Dr. Robert Jackler of Stanford Medicine and Stanford Research into the Impact of Tobacco Advertising ("SRITA") testified before the House of Representatives that Mr. Monsees indicated to him that JUUL had found SRITA's database of tobacco advertisements "helpful" in developing JUUL's advertising.⁴⁴¹

2. Campaign Components

To reach consumers, the Vaporized campaign included a mix of traditional and digital marketing—namely advertisements placed online, in magazines, and on billboards—as well as social media influencers and experiential marketing.

Traditional and Digital Marketing. The Vaporized campaign's traditional and digital advertisements featured not only the JUUL product, but also models demonstrating the product against a backdrop of bright colors, including neon yellow, teal, and pink. The models included "10 New York trendsetters"—including an animator, a photographer, and DJ, among others—"who embod[ied] the JUUL brand and [spoke] to millennial consumers seeking a stylish and simple new way to enjoy nicotine with the latest vapor technology."⁴⁴²



Figure 5: Advertisements from the JUUL Vaporized Campaign⁴⁴³

JUUL placed advertisements on radio and print media, as well as in digital media, including the Vice, Gawker, Hypebeast, Spin Media, Thrillist, and Urban Daddy

⁴³⁹ Kania Interview (Nov. 15, 2019).

⁴⁴⁰ *Id.*

⁴⁴¹ *Examining JUUL's Role in the Youth Nicotine Epidemic: Part I: Hearing Before the Subcomm. on Econ. and Consumer Pol'y of the H. Comm. on Oversight and Reform*, 116th Cong. 17 (2019) (statement of Dr. Robert Jackler, Professor, Stanford University).

⁴⁴² JLI-PSI-00029687. JUUL cast models similar to the company's target demographic of 25-to-34 year-old consumers; the average age of the models in the Vaporized campaign was 29, with the youngest model and oldest model being 24 and 37, respectively. Kania Interview (Nov. 15, 2019); JLI-PSI-00361222–23. Internal notes reflect that JUUL viewed this age range and its marketing approach as different from the approach of its competitors, which JUUL viewed as "irresponsible" for "target[ing] [a] younger male demographic." JLI-PSI-00433861.

⁴⁴³ JLI-PSI-00371076.

websites.⁴⁴⁴ Cult Collective recommended collaborating with these websites to “[p]osition JUUL as a cool brand and unique product” and “[b]uild [a]wareness for JUUL among the target,” which Cult Collective described as “[a]dults 18-34, who smoke, [and] are early adopters that are trendy.” For example, Cult Collective described UrbanDaddy as a site that “engage[d] influencers who seek high-end lifestyles in all aspects,” with “73% of [its] total audience [between] ages 18-34.”⁴⁴⁵ Cult Collective focused on individuals aged 18 to 34, despite JUUL allegedly targeting older consumers above the age of 25.⁴⁴⁶

The traditional advertising component of the Vaporized campaign also included digital billboards in Times Square, which showed JUUL’s advertisements for four weeks.⁴⁴⁷ The company received “4,493 minutes of air time” and “roughly 1.5MM impressions/day, or 42MM impressions over the entire flight.”⁴⁴⁸

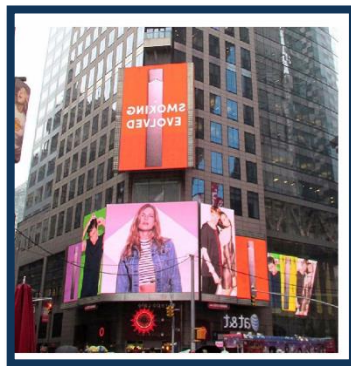


Figure 6: Vaporized Times Square Billboards⁴⁴⁹

Alleged Advertisements on Youth-Focused Websites. On February 12, 2020, Massachusetts Attorney General Maura Healey filed a complaint against JUUL alleging, in part, that the company placed Vaporized campaign images on websites that were “highly attractive to children, adolescents in middle school and high school, and underage college students.”⁴⁵⁰ Specifically, JUUL allegedly purchased advertisements

⁴⁴⁴ JLI-PSI-00034189–90; JLI-PSI-00347153.

⁴⁴⁵ JLI-PSI-00036638.

⁴⁴⁶ *Id.*

⁴⁴⁷ JLI-PSI-00033221; JLI-PSI-00450981.

⁴⁴⁸ JLI-PSI-00034189.

⁴⁴⁹ JLI-PSI-00371221.

⁴⁵⁰ Complaint at 16–17, *Massachusetts v. JUUL Labs, Inc. & Pax Labs, Inc.*, No. 20-0402, 2020 WL 6787752 (Mass. Super. Feb. 12, 2020), <https://www.mass.gov/doc/juul-complaint/download> [hereinafter *Massachusetts Complaint*]. On April 12, 2023, JUUL reached a \$462 million settlement with the Massachusetts Office of Attorney General and six other state attorneys general, including New York, California, Colorado, the District of Columbia, Illinois, and New Mexico. Christina Jewett & Julie Creswell, *Juul Reaches \$462 Million Settlement With New York, California and Other States*, N.Y. TIMES (Apr. 12, 2023), <https://www.nytimes.com/2023/04/12/health/juul-vaping-settlement-new-york-california.html>.

on websites like nick.com, nickjr.com, cartoonnetwork.com, teen.com, seventeen.com, coolmath-games.com, allfreekidscrafts.com, and socialstudiesforkids.com.⁴⁵¹

JUUL denied that it intentionally targeted websites appealing to underage users.⁴⁵² The company explained to the Subcommittee that it hired Mediasmith, a media buying company, to conduct direct and programmatic media buys for its Vaporized campaign advertisements in 2015.⁴⁵³ Mediasmith assessed internet users within JUUL's target audience and placed advertisements on websites they viewed.⁴⁵⁴ Initially, JUUL provided guidance instructing Mediasmith to target users aged 25 to 49, but the company later shifted this age range to 18 to 34 to conform to marketing industry standards.⁴⁵⁵ Mediasmith was also instructed to target 18-to-34 year olds who had "smoked a cigarette/eCig in the last year" and were "[f]ashionable, urban, with a vibrant life," "[t]ech savvy and an early adopter," and "enjoy[ed] going out to shows and events."⁴⁵⁶ JUUL claims it relied on Mediasmith to target the appropriate audience in its media buys.⁴⁵⁷

In correspondence with the Subcommittee, JUUL stated it believes the allegations in the Massachusetts complaint derived from a Mediasmith spreadsheet sent to JUUL's then-Vice President of Digital Commerce in June 2016.⁴⁵⁸ The spreadsheet listed the websites on which Mediasmith placed advertisements, the number of advertisements placed on each website, and the number of interactions web users had with those advertisements.⁴⁵⁹ The spreadsheet listed the 30 websites cited in the Massachusetts complaint as appealing to youth and young adults.⁴⁶⁰ Specifically,

⁴⁵¹ Massachusetts Complaint, *supra* note 450, at *17–18. Other websites cited by the Massachusetts complaint include: hellokids.com, kidsgameheroes.com, dailydressupgames.com, didigames.com, forhergames.com, games2girls.com, girlgames.com, girlsogogames.com, basic-mathematics.com, coolmath.com, math-aids.com, mathplayground.com, mathway.com, onlinemathlearning.com, purplemath.com, justjaredjr.com, hireteen.com, collegeconfidential.com, collegeview.com, collegehumor.com, thecollegeprepster.com, and survivingcollege.com. *Id.*

⁴⁵² Briefing with Counsel for JUUL Labs, Inc. (Mar. 13, 2020); Letter from Counsel for JUUL Labs, Inc. to the Subcommittee (Apr. 28, 2020).

⁴⁵³ Letter from Counsel for JUUL Labs, Inc. to the Subcommittee (Apr. 28, 2020); JLI-PSI-00451164. Direct media buys involve placing digital advertisements directly on specific websites that target an adult audience, whereas programmatic media buys entail "reach[ing] a target audience . . . without specifying any particular website." Letter from Counsel for JUUL Labs, Inc. to the Subcommittee (Apr. 28, 2020).

⁴⁵⁴ Letter from Counsel for JUUL Labs, Inc. to the Subcommittee (Apr. 28, 2020).

⁴⁵⁵ JLI-PSI-00430618; Briefing with Counsel for JUUL Labs, Inc. (Mar. 13, 2020). JUUL counsel noted that "at no time did [the target audience] include individuals under 18 years of age." Letter from Counsel for JUUL Labs, Inc. to the Subcommittee (Apr. 28, 2020).

⁴⁵⁶ JLI-PSI-00451333.

⁴⁵⁷ Letter from Counsel for JUUL Labs, Inc. to the Subcommittee (Apr. 28, 2020).

⁴⁵⁸ JLI-PSI-00451122; Letter from Counsel for JUUL Labs, Inc. to the Subcommittee (Apr. 28, 2020). JUUL believes this individual was the only recipient of the spreadsheet. Briefing with Counsel for JUUL Labs, Inc. (Mar. 13, 2020); Letter from Counsel for JUUL Labs, Inc. to the Subcommittee (Apr. 28, 2020).

⁴⁵⁹ JLI-PSI-00451123; Briefing with Counsel for JUUL Labs, Inc. (Mar. 13, 2020); Letter from Counsel for JUUL Labs, Inc. to the Subcommittee (Apr. 28, 2020).

⁴⁶⁰ JLI-PSI-00451123; Briefing with Counsel for JUUL Labs, Inc. (Mar. 13, 2020); Letter from Counsel for JUUL Labs, Inc. to the Subcommittee (Apr. 28, 2020).

approximately 71,000 placements—out of over 25 million placements across 10,000 websites—were associated with the 30 websites.⁴⁶¹ Out of these placements, approximately 67,700 (or 95 percent) were on coolmath-games.com, and the remaining approximately 3,500 were associated with the other 29 websites—with many of the websites having fewer than 100 placements.⁴⁶² According to JUUL, these roughly 71,000 placements resulted in 40 “clicks”—38 clicks from coolmath-games.com and two from socialstudiesforkids.com—and led to zero purchases of JUUL products.⁴⁶³

JUUL disputed the reliability of the spreadsheet because certain information appears to deviate from industry standards. According to JUUL, companies typically purchase placements by the thousand, for example, and the spreadsheet contains entries with less than 1,000 placements.⁴⁶⁴ JUUL also noted that, although a vendor may place advertisements on websites, internal controls on each website might prevent advertisements from actually appearing.⁴⁶⁵ JUUL informed Subcommittee staff that it reached out to the media companies that own several of the websites cited in the Massachusetts complaint and learned that their systems are designed to prevent inappropriate advertisements—for age-restricted products, for example—from appearing on their websites.⁴⁶⁶ According to the company, for example, cartoonnetwork.com does not accept programmatic advertisements altogether and would not have displayed any JUUL advertisements from the Mediasmith media buy, despite it being one of the websites listed on the spreadsheet.⁴⁶⁷

Experiential Marketing. In addition to traditional and digital media marketing, JUUL promoted its products through experiential marketing—such as launch parties and other sponsorships in which guests could sample products for free or a minimal charge.⁴⁶⁸ On June 4, 2015, JUUL officially launched its product with a party in New York City that “attracted key influencers [and] amplified press buzz throughout the week.”⁴⁶⁹ According to a description of the party published in one media outlet, the “smoking hot party” featured a “live photo shoot / modeling session . . . a packed dance floor due to the on-point DJ sets . . . bites by [a] Top Chef winner . . . , and of course,

⁴⁶¹ Briefing with Counsel for JUUL Labs, Inc. (Mar. 13, 2020); Letter from Counsel for JUUL Labs, Inc. to the Subcommittee (Apr. 28, 2020).

⁴⁶² Briefing with Counsel for JUUL Labs, Inc. (Mar. 13, 2020); Letter from Counsel for JUUL Labs, Inc. to the Subcommittee (Apr. 28, 2020).

⁴⁶³ “Clicks” refers to instances in which users clicked on an advertisement directing them to the JUUL website. Briefing with Counsel for JUUL Labs, Inc. (Mar. 13, 2020); Letter from Counsel for JUUL Labs, Inc. to the Subcommittee (Apr. 28, 2020).

⁴⁶⁴ Letter from Counsel for JUUL Labs, Inc. to the Subcommittee (Apr. 28, 2020).

⁴⁶⁵ *Id.*

⁴⁶⁶ Briefing with Counsel for JUUL Labs, Inc. (Mar. 13, 2020).

⁴⁶⁷ *Id.* In addition, counsel for JUUL informed Subcommittee staff that Turner Broadcasting System, owner of Cartoon Network, conducted its own investigation into the impressions associated with cartoonnetwork.com and believes that JUUL advertisements did not appear on the website. *Id.*

⁴⁶⁸ JUUL provided free samples in 2015, but the company stopped this practice after FDA’s deeming rule went into effect on August 8, 2016, subjecting e-cigarettes to the laws and regulations under the Family Smoking Prevention and Tobacco Control Act and prohibiting the distribution of free products. Since the effective date of the deeming rule, JUUL has provided “coupons or discount codes through which consumers can purchase product at a discount” on its website. JLI-PSI-00450938–39.

⁴⁶⁹ JLI-PSI-00034190.

cocktails and a full vape bar.”⁴⁷⁰ Nearly 400 guests attended the party, including members of the press from BuzzFeed, Huffington Post, Gizmodo, and The Daily Beast, as well as over 100 influencers who were photographed and, in some cases, later featured in JUUL’s Times Square billboard campaign.⁴⁷¹ In addition, “200 attendees amplified word-of-mouth via social media tagging/posting, touching 26K people.”⁴⁷² JUUL spent around \$120,000 on the launch party.⁴⁷³



Figure 7: Images from the JUUL Launch Party⁴⁷⁴

The Vaporized campaign also included a “sampling tour,” which at times utilized a portable pop-up shop, mainly in the New York City and Los Angeles areas—“two of the most trend-setting cities in the US.”⁴⁷⁵ Through the sampling tour, JUUL hoped to introduce people to company products and provide samples and information for repeat purchase.⁴⁷⁶ One internal document noted that the “[c]ontainer tour [would] get JUUL into the hands of over 12,500 influencers [and] introduce the product to over 1.5 million people.”⁴⁷⁷ At the “sampling tour kick-off” on June 5-6, 2015, JUUL “gifted 1.3K starter kits,” which exceeded the company’s goal of distributing 1,000 kits.⁴⁷⁸ JUUL also held in-store sampling events at retail locations in 11 states.⁴⁷⁹

⁴⁷⁰ *We Got #VAPORIZED: Inside the JUUL Launch Party*, GUEST OF A GUEST (June 16, 2015), <https://guestofaguest.com/new-york/events/we-got-vaporized-inside-the-juul-launch-party>.

⁴⁷¹ JLI-PSI-00034190.

⁴⁷² *Id.*

⁴⁷³ JLI-PSI-00371221.

⁴⁷⁴ JLI-PSI-00269196; JLI-PSI-00269231; JLI-PSI-00269311.

⁴⁷⁵ JLI-PSI-00044502; JLI-PSI-00371076-77; JLI-PSI-00450963.

⁴⁷⁶ JLI-PSI-00044504.

⁴⁷⁷ *Id.*

⁴⁷⁸ JLI-PSI-00034190.

⁴⁷⁹ JLI-PSI-00450925.

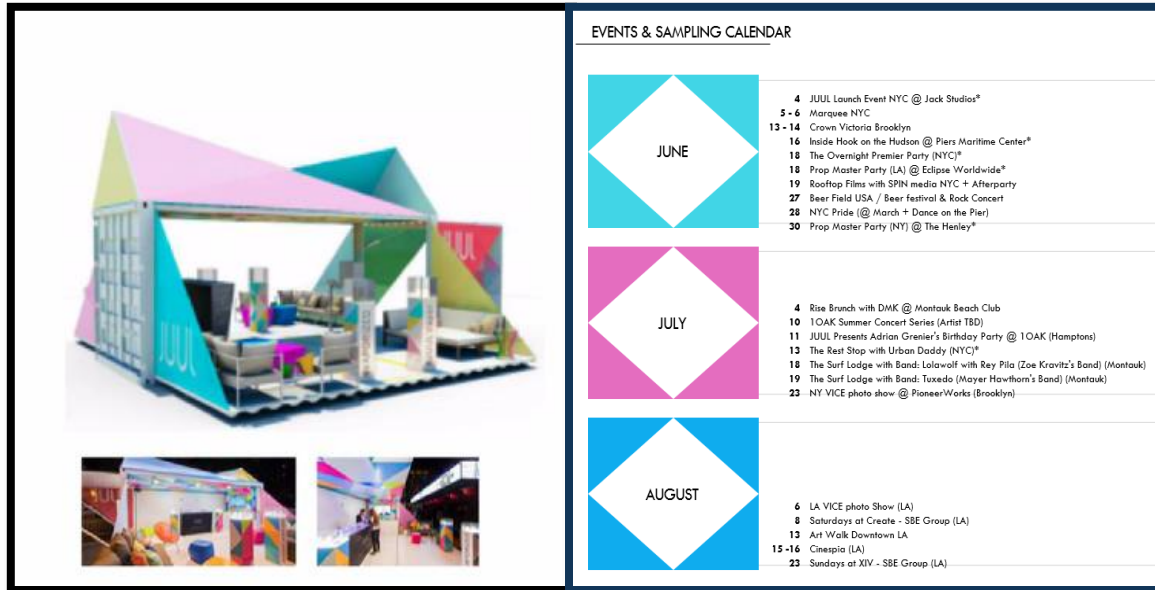


Figure 8: Vaporized Traveling Pop-Up Container Shop (left)⁴⁸⁰ and JUUL 2015 Launch Events and Sampling Calendar (right)⁴⁸¹

JUUL also sponsored events, including booths and pop-ups at movie premieres, the NYC Pride March, food and wine festivals, concerts, and other large gatherings.⁴⁸² At these events, JUUL generally distributed product samples and coupons and provided an open bar, hors d'oeuvres, a photo booth, and other JUUL-branded products such as koozies and iPhone cases.⁴⁸³ According to a June 2015 monthly report, the company distributed 2,100 coupons and gifted 5,017 starter kits at JUUL events that month.⁴⁸⁴ In addition, 3,500 people visited the sampling tour container, and the ten sponsored events that month had over 20,000 “event impressions.”⁴⁸⁵ In 2015, JUUL spent over \$1.1 million on brand sponsorships and tradeshow.⁴⁸⁶

⁴⁸⁰ JLI-PSI-00371077.

⁴⁸¹ JLI-PSI-00259151.

⁴⁸² JLI-PSI-00450963.

⁴⁸³ JLI-PSI-0050395-412.

⁴⁸⁴ JLI-PSI-00239402.

⁴⁸⁵ *Id.*

⁴⁸⁶ JLI-PSI-00450949.



Figure 9: Images from JUUL Sponsored Events in June 2015⁴⁸⁷

Influencer Marketing. JUUL also advertised its e-cigarette products via word of mouth through “influencers”—celebrities and other individuals with a large social media presence. JUUL hired Grit Creative Group (“Grit”), a marketing agency, to identify “celebrities [and] other high profile individuals who smoke cigarettes and convert them into JUUL customers, or to increase the loyalty of high-profile celebrities who [were] existing JUUL customers.”⁴⁸⁸ As part of the JUUL launch, Grit and JUUL invited influencers to sponsored events and gifted product samples to approximately 163 individuals.⁴⁸⁹ Notable influencers included model and actress Cara Delevingne, actress Jemima Kirke, singer Miley Cyrus, and model Luka Sabbat.⁴⁹⁰ As the company noted, “[t]he purpose of these efforts was to increase JUUL’s exposure through individuals with large audiences.”⁴⁹¹



Figure 10: Sample of Celebrity Pictures in the “JUUL Influencer Seeding Chart” by Grit⁴⁹²

⁴⁸⁷ JLI-PSI-00030355; JLI-PSI-00438813–27.

⁴⁸⁸ JLI-PSI-00450942.

⁴⁸⁹ JLI-PSI-00450935; JLI-PSI-00450942–43.

⁴⁹⁰ JLI-PSI-00435514–27.

⁴⁹¹ JLI-PSI-00450943.

⁴⁹² JLI-PSI-00435514–27.

Apart from Grit, JUUL reached out to an additional 236 influencers.⁴⁹³ By August 2015, additional influencers scheduled to receive free JUUL products included musician Joe Jonas, actors Ashton Kutcher, Aubrey Plaza, and Gal Gadot, and comedian Wyatt Cenac.⁴⁹⁴ According to JUUL, influencers who received free products were “not asked to do anything in exchange for receiving JUUL products.”⁴⁹⁵

Although not part of the Vaporized campaign, JUUL used one celebrity in a testimonial—actress Nora Lum, also known as Awkwafina.⁴⁹⁶ Ms. Lum, who was 29 years old at the time, starred in a user testimonial in February 2018 after transitioning from traditional cigarettes to JUUL.⁴⁹⁷ She did not receive paid compensation for her testimonial but instead received product discounts through JUUL’s “VIP Club.”⁴⁹⁸



Figure 11: Actress Nora Lum (“Awkwafina”) Testimonial Video Images⁴⁹⁹

3. Concept Testing

In developing the Vaporized campaign, neither JUUL nor Cult Collective considered whether the campaign’s elements might appeal to underage audiences.⁵⁰⁰ According to Ms. Kania, JUUL was not “thinking at all” about the potential for youth appeal prior to the June 2015 launch,⁵⁰¹ despite decades of evidence to support a connection between the marketing of nicotine-based products and youth appeal.⁵⁰² In

⁴⁹³ JLI-PSI-00036884.

⁴⁹⁴ *Id.*

⁴⁹⁵ JLI-PSI-00450943.

⁴⁹⁶ JLI-PSI-00450938.

⁴⁹⁷ *Id.*; JLI-PSI-00379540.

⁴⁹⁸ JLI-PSI-00450938. The “VIP Club” is a premium e-commerce portal for “a small number of high-profile celebrities” who are JUUL e-commerce customers and over the age of 28. JUUL offers discounts and advance access to limited edition products to club members. As of October 2018, JUUL had 10 active VIP Club members and four individuals who had not activated their accounts. JLI-PSI-00450944.

⁴⁹⁹ JLI-PSI-00379550.

⁵⁰⁰ Kania Interview (Nov. 15, 2019).

⁵⁰¹ *Id.*

⁵⁰² See 2012 SURGEON GEN. REP., *supra* note 11. “Tobacco companies have long argued that their marketing efforts do not increase the overall demand for tobacco products and have no impact on the initiation of tobacco use among young people; rather, they argue, they are competing with other companies for market share. In contrast, the weight of the evidence from extensive and increasingly sophisticated research conducted over the past few decades shows that the industry’s marketing

fact, neither company concept-tested or analyzed its marketing message in advance of the campaign's launch.⁵⁰³ In her interview with Subcommittee staff, Ms. Kania blamed limited resources and the small size of JUUL prior to the Vaporized campaign for the absence of due diligence concerning youth appeal.⁵⁰⁴ She explained that the company's marketing team looked through the "narrow lens" of how to spend its budget efficiently to find the most likely consumers.⁵⁰⁵ She further noted that during this period, expenditures for projects "without a strong rationale behind them were hard to come by."⁵⁰⁶

B. Social Media

From the start of the Vaporized campaign, JUUL created and ran accounts on Facebook, Instagram, Twitter, and YouTube as part of its marketing efforts.⁵⁰⁷ By November 2018, JUUL's Instagram, Twitter, and Facebook accounts had 77,600, 19,700, and 10,280 followers, respectively.⁵⁰⁸ Not only did JUUL benefit from its own created content, but it also sponsored influencers and spurred extensive user-generated conduct, including posts and memes geared toward younger populations.

JUUL-Generated Content. Prior to November 2018—when JUUL stopped actively advertising on social media—its promotional activities on social media included posts featuring product images, customer testimonials, flavor images, and lifestyle themes like relaxation, freedom, and sex appeal.⁵⁰⁹ JUUL used a number of hashtags, including: #JUUL; #SwitchToJUUL; #juulnation; #juulpods; #juulvapor; #juulmoments; #mango; #sharejuul; #cremebrulee; #classicmenthol; #coolcucumber; #fruitmedley; #virginiatobacco; #coolmint; #juulinhand; #juullife; #juulnation; #thesmokingalternative; and #vaporized.⁵¹⁰ A 2019 SRITA study on JUUL and social media found that the company "extensively used" hashtags, which "greatly expand[ed] the reach of the company's social media postings."⁵¹¹ The study also found that JUUL increased its use

activities have been a key factor in leading young people to take up tobacco, keeping some users from quitting, and achieving greater consumption among users." *Id.* at 487.

⁵⁰³ Kania Interview (Nov. 15, 2019).

⁵⁰⁴ *Id.*

⁵⁰⁵ *Id.*

⁵⁰⁶ *Id.*

⁵⁰⁷ JUUL, FACEBOOK, www.facebook.com/juulvapor/; JUUL (@Juulvapor), INSTAGRAM, www.instagram.com/juulvapor/; Juul Labs, YOUTUBE, www.youtube.com/channel/UCpZDjAIOA4XdgV4dYArwbgw; JLI-PSI-00450924; Letter from Counsel for JUUL Labs, Inc. to the Subcommittee (Aug. 21, 2019).

⁵⁰⁸ Robert Jackler et al., *JUUL Advertising Over its First Three Years on the Market*, STAN. UNIV. SCH. MEDICINE 19 (2019).

⁵⁰⁹ Huang et al., *supra* note 63, at 149.

⁵¹⁰ JLI-PSI-00450924. JUUL also used the following hashtags: #JUULfacts; #JUULtips; #juulmoment; #fathersday; #juulpods; #mothersday; #taxseason; #mango; #nyc; #juulnyc; #tgif; #juulmiami; #miami; #classictobacco; #TBT; #juulhandcheck; #mangomondays; #fruitfriday; #laborday; #mintpod; #tobaccotuesday; #CyberMonday; #smoker; #smokers; #cigarettes; #Fall; #BestDesignFC; #CaliforniaBeerFestival; #JUULxCBF; #BiteofLasVegas; #BiteLV; #ICYMI; #JUULallnight; #LosAngeles; #Cinespia. *Id.*

⁵¹¹ Jackler et al., *supra* note 508, at 23.

of hashtags “substantially” in 2018, compared to its first year on the market in 2015.⁵¹² According to Dr. Jackler, JUUL’s presence on social media was a “phenomenon that took on a life of its own” and “[h]ashtag-Juul lives on.”⁵¹³ In September 2020, for example, the #juul hashtag appeared on over 708,000 posts on Instagram, although the hashtag later became “hidden” on the platform.⁵¹⁴ When the Subcommittee reviewed the platform in January 2021, thousands of posts with various hashtags related to JUUL still appeared on Instagram. For example, #juulpods appeared on over 81,400 posts; #juulmemes appeared on over 65,300 posts; #juulnation appeared on over 63,100 posts; and #juulgang appeared on over 62,800 posts.⁵¹⁵ As of October 2023, over 32,500 posts appeared for #juulpods; #juulmemes appeared on over 50,600 posts; #juulnation was tagged on 28,200 posts; and #juulgang appeared on over 32,700 posts. Most notably, the #juul hashtag was not “hidden” and appeared on over 524,000 posts.⁵¹⁶

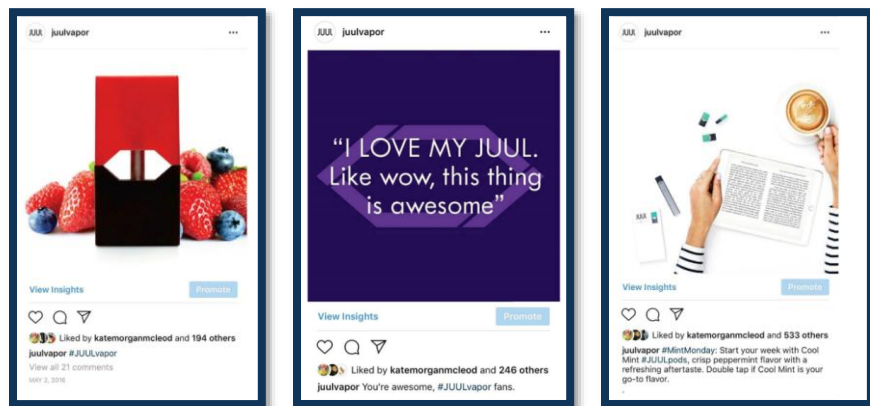


Figure 12: Examples of JUUL Instagram Posts⁵¹⁷

⁵¹² *Id.* at 23–26.

⁵¹³ Michael Nedelman et al., *#JUUL: How Social Media Hyped Nicotine for a New Generation*, CNN (Dec. 19, 2018), <https://www.cnn.com/2018/12/17/health/juul-social-media-influencers/index.html>.

⁵¹⁴ Results for “#juul,” INSTAGRAM (searched Sept. 2020). According to Instagram, “Posts for #juul have been limited because the community has reported some content that may not meet Instagram’s community guidelines.” Screenshot from Instagram (Jan. 5, 2021) (image on file with the Subcommittee).

⁵¹⁵ Results for “#juul,” INSTAGRAM (searched Jan. 5, 2021).

⁵¹⁶ Results for “#juul,” INSTAGRAM (last searched Oct. 25, 2023).

⁵¹⁷ JLI-PSI-00027836; JLI-PSI-00027913; JLI-PSI-00028172.

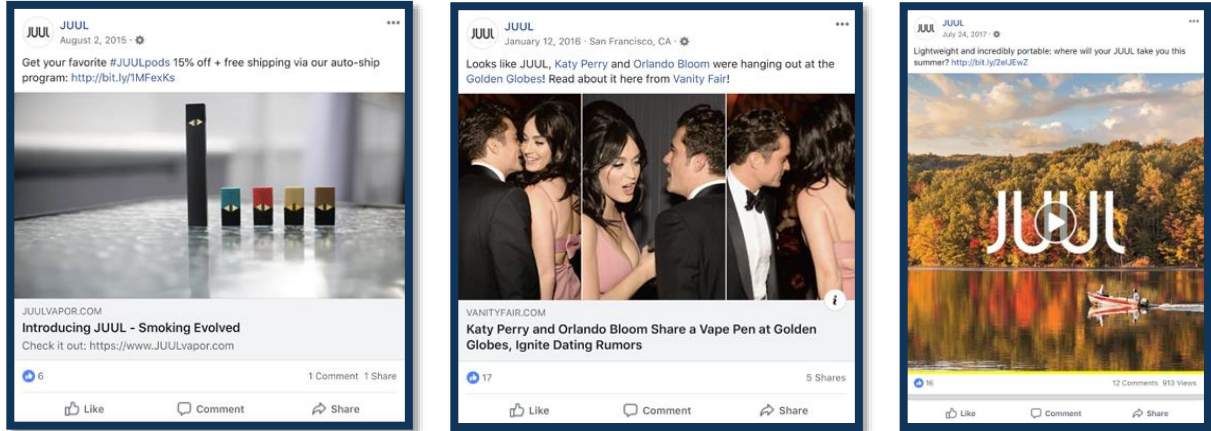


Figure 13: Examples of JUUL Facebook Posts⁵¹⁸

JUUL-Sponsored Social Media Influencers. As it did with the Vaporized campaign, JUUL sponsored social media influencers to promote JUUL products. In the fall of 2017, JUUL engaged Lumanu, a media firm, to identify social media influencers who would receive paid compensation to post JUUL-related content to their social media accounts and blogs.⁵¹⁹ JUUL directed Lumanu to find influencers who were smokers, or recent smokers, over age 30, and had an audience in which 85 percent of their followers were aged 21 and over.⁵²⁰ Overall, JUUL paid a total of \$8,500 to four individuals to post JUUL-related content on Instagram and in blog posts.⁵²¹ JUUL ended the social media influencer program in December 2017.⁵²²

Influencer	Amount Paid	Blog and Social Media Posts
<u>Laura Ellner</u> fashion blogger	\$3,500	<ul style="list-style-type: none"> • Two blog posts (http://ontheracks.com) • Four Instagram posts (@ontheracks)
<u>Joe Miriagliotta</u> lifestyle / travel blogger	\$2,500	<ul style="list-style-type: none"> • One blog post (https://joesdaily.com) • One Instagram post (@joesdaily)

⁵¹⁸ Jackler et al., *supra* note 508; *Collection: Facebook*, Rsch. into the Impact of Tobacco Advert., STAN. UNIV., <https://tobacco.stanford.edu/pods/juul/facebook/>.

⁵¹⁹ JLI-PSI-00450937.

⁵²⁰ JLI-PSI-00450943; JLI-PSI-00100651.

⁵²¹ JLI-PSI-00450937; JLI-PSI-00099070. In addition to the four influencers, JUUL engaged two other influencers to participate in user testimonials. Lauren Hastings, a professional model who had approximately 30,500 Instagram followers on her Instagram accounts @itslaurenastings and @laurenastings, participated in a user testimonial and was provided discount codes in return. JUUL also covered the expenses for her trip to film the testimonial. Otherwise, Ms. Hastings did not receive paid compensation for her participation. JUUL noted that Ms. Hastings posted images of JUUL on her social media accounts, but these images were not at the request of the company. Similarly, William “Carl” Radke, a producer and reality television actor with approximately 80,000 Instagram and 9,500 Twitter followers on his Instagram and Twitter handle @carlradke, participated in a testimonial for JUUL and received discount codes. Mr. Radke also posted images of JUUL on social media, but these posts were not at JUUL’s request. JLI-PSI-00450976.

⁵²² Briefing with JUUL Labs, Inc. (May 15, 2019).

Christian Bendek lifestyle blogger ⁵²³	\$1,500	• One Instagram post (@CaribbeanKing)
Christina Zayas lifestyle influencer	\$1,000	• One blog post (http://lecitykitty.com) • One Instagram post (@christinazayas)

Figure 14: JUUL-Sponsored Social Media Influencers in 2017⁵²⁴

One of the paid influencers, Christina Zayas, said the company “liked [her] edgy style and that [she] appealed to the younger market.”⁵²⁵ Although the majority of her followers were aged 18 to 35, five percent of her Instagram audience were aged 13 to 17.⁵²⁶ Her JUUL-sponsored Instagram post reached more than 4,500 people and received approximately 1,500 likes.⁵²⁷

User-Generated Social Media Content. Although JUUL has claimed it engaged in limited social media marketing, the company benefited from a vast amount of user-generated social media content. In fact, an April 2018 audit JUUL commissioned from a third party stated: “[T]here is also a huge community of underage users running fan & meme pages about JUULing.”⁵²⁸ The company has acknowledged that the “vast majority of images and accounts attributed to JUUL that have featured youth-oriented content actually belong to third parties, who are entirely unaffiliated with and unauthorized by JUUL Labs.”⁵²⁹

Much of the user-generated content was geared towards youth. One study that analyzed over 14,800 user-generated JUUL-related Instagram posts between March and May 2018 found that 55 percent of the posts had youth-related content, including posts involving memes, cartoon images, flavors, JUUL use in class, or celebrity references, and 57 percent had lifestyle-related content, including posts related to JUUL use during social activities and “JUULing.”⁵³⁰ A second phase of the study analyzed over 35,900 JUUL-related Instagram posts between May and November 2018 and found that the content remained unchanged over time despite JUUL’s efforts to remove content in May 2018.⁵³¹ The study concluded that “self-regulatory actions undertaken [by JUUL] did not decrease the overall volume of JUUL-related content.”⁵³² Another analysis of 526 Instagram posts tagged with the #juul hashtag and collected over two

⁵²³ In February 2018, JUUL paid an additional \$1,000 for Mr. Bendek to share and link a 2015 Wired Magazine article about JUUL on his Facebook page. JLI-PSI-00450937.

⁵²⁴ *Id.*; JLI-PSI-00099070. According to JUUL, these payments represented “the only direct compensation paid by the Company to any individuals to post their own JUUL-related content on social media or elsewhere.” JLI-PSI-00450937. JUUL is “unable to calculate what amount of its sales, if any, can be attributed” to these sponsored posts. JLI-PSI-00450938.

⁵²⁵ Nedelman et al., *supra* note 513.

⁵²⁶ *Id.*

⁵²⁷ *Id.*

⁵²⁸ JLI-PSI-00166122.

⁵²⁹ Briefing with JUUL Labs, Inc. (May 15, 2019).

⁵³⁰ Czaplicki et al., *supra* note 105.

⁵³¹ Czaplicki et al., *#toolittletoolate: JUUL-related content on Instagram before and after self-regulatory action*, PLoS ONE 15(5):e0233419 (May 21, 2020).

⁵³² *Id.*

weeks in mid-2018 revealed that 68.8 percent of posts (362 out of 526) were “youthful” and commonly showed “humor (40.7%), memes (31.2%), and pop culture references (29.1%).”⁵³³



Figure 15: Examples of User-Generated JUUL-Related Instagram Posts⁵³⁴

A study on user-generated JUUL-related content on Twitter between 2015 and 2017 showed that JUUL-related tweets were “scarce” in 2015 (8,416), more than doubled in 2016 (21,292), and “exploded” in 2017 (366,786).⁵³⁵ The same study reviewed 35 JUUL-related YouTube videos on the platform on March 1, 2018, and found that these videos—a majority of which had been posted in 2017—had over 8 million views and received over 51,000 likes. The majority of these videos were product reviews, and a dozen of the videos showed how to modify the JUUL device.⁵³⁶ Additionally, the study found that in 23 of these videos, “the persons appearing in the video were either youth or young adults.”⁵³⁷

IV. JUUL KNEW IT APPEALED TO YOUTH BUT FAILED TO PREVENT YOUTH PURCHASES OF ITS PRODUCTS

Before the 2015 launch of the Vaporized campaign, JUUL received feedback that the overall “youthfulness” of the campaign risked attracting youth to its products. Similarly, for years after the campaign, JUUL employees and consultants, as well as other third parties, repeatedly warned of the danger of JUUL products and marketing resonating with youth.⁵³⁸ Yet, despite knowing that its tactics were successful in driving

⁵³³ Jackler et al., *supra* note 509, at 23.

⁵³⁴ *Id.*; Czaplicki et al., *supra* note 105.

⁵³⁵ Huang et al., *supra* note 63, at 148.

⁵³⁶ *Id.* at 149.

⁵³⁷ *Id.*

⁵³⁸ For example, after a presentation to the JUUL Board of Directors regarding a media plan focused on the New York area, the Director of Media & Customer Acquisition wrote that the plan “raised a couple concerns about creative messaging and accurate targetability of the media. . . . What we need to do now is educate the [sic] board on media targeting tactics and as well as the the [sic] ways we can ensure [the] message is NOT reaching an unintended, young audience.” JLI-PSI-00142789. Similarly, Bruce Harter, a consultant for the Education & Youth Prevention department, stated in March 2018: “There always has to be a threat or an enemy and JUUL is a perfect target because JUULs are incredibly popular with students.” JLI-PSI-00152940. He continued:

youth use, JUUL did not adequately respond to or prevent youth purchase of its products.

JUUL did undertake some efforts to discourage youth from using its products. For example, JUUL rebranded itself, moving away from the bright, flashy imagery used in the Vaporized campaign. On social media, JUUL began monitoring “[i]nappropriate use of JUUL,” “[t]rends,” and “[u]nderage use/content,” among other issues, and seeking enforcement “against sellers of our products on third party sites.”⁵³⁹ These efforts, however, did little to counteract JUUL’s popularity among youth.

JUUL has also been unsuccessful in preventing youth purchases of its products. Beginning in 2015, JUUL contracted with Veratad Technologies, LLC (“Veratad”) for age verification services to ensure purchasers on JUUL’s website were of legal age.⁵⁴⁰ However, company documents show that JUUL’s age verification system, as well as its customer service process, suffered from numerous vulnerabilities that allowed youth to obtain JUUL products. Finally, the company knew that “social sourcing”—in which the youngest legal users of JUUL products sold or gave them to underage peers—fueled high school and middle school e-cigarette use but never made any effort to combat the problem.

A. Only After Receiving Negative Feedback about the Youthfulness of the Vaporized Campaign, JUUL Rebranded and Attempted to Remove Traces of Vaporized Imagery

JUUL received negative feedback both before and after the launch of the Vaporized campaign about the campaign’s overall “youthfulness” and attractiveness to youth and young adults. In the months and years following the launch, JUUL sought to separate itself from the Vaporized campaign, including by rebranding and trying to remove traces of Vaporized imagery. These efforts, however, fell short, as JUUL continued to resonate with youth.

JUULs are so attractive to young people right now that just about everyone in the upper middle class schools has one or uses one. At the school where I was yesterday, the principal’s freshman son has been caught three times with a JUUL. . . . The [school resource officers] at the school said they’d issued 46 citations in the last month for underage JUUL possession and they believe they’re just at the very tip of the iceberg of users. JLI-PSI-00152940.

Mr. Harter later wrote that “JUUL created a product to save lives by putting combustible cigarettes out of business. The unintended consequence is that teenagers find JUULs irresistible.” JLI-PSI-00153201. Ms. Henderson stated that she did not agree that students found JUUL products “irresistible” and that this sentiment was an exaggeration. She said JUUL products were “tempting and attractive but not irresistible.” She further noted that the price of JUUL devices meant that children, in general, could not afford them. Henderson Interview (Nov. 22, 2019).

⁵³⁹ JLI-PSI-00002820; JLI-PSI-00004262; Henderson Interview (Nov. 22, 2019).

⁵⁴⁰ Massachusetts Complaint, *supra* note 450.

1. JUUL Recognized the Youthfulness of the Vaporized Campaign but Failed to Consider How It Might Appeal to Youth and Young-Adults

The 2015 Vaporized campaign’s colorful advertisements, trendy parties, and use of celebrities and social media influencers made JUUL’s products popular among youth and young adults.⁵⁴¹ As explained above, JUUL failed to consider youth appeal when developing the Vaporized campaign—despite long-standing problems with youth appeal in the nicotine industry.⁵⁴² In working to disrupt the tobacco industry model, JUUL failed to avoid long-established pitfalls associated with selling nicotine products, including the appeal of a “cool and playful” marketing campaign to youth and young adults.

Despite a lack of concept-testing, the company knew elements of the Vaporized campaign were “youthful.” Three months before the launch of the campaign, a director’s meeting about the JUUL teaser website included “commentary at the youthfulness of the models . . . nobody disliked them, everybody agreed they are pretty ‘effective.’”⁵⁴³ The JUUL Board of Directors also raised concerns about the youthfulness of the brand generally. For example, in June 2015, the Chief Operating Officer at the time emailed the then-Chief Marketing Officer: “The JUUL brand has come up as a discussion point at each board call this month, but never as a top level concern. You may recall [board member] Nick [Pritzker] saying ‘it feels too young’ . . . The weekly calls have a similar tone”⁵⁴⁴ The Chief Operating Officer suggested having the creative team consider how they should change JUUL’s branding and messaging.⁵⁴⁵

Internal documents show Ms. Kania also recognized the youthfulness of the Vaporized campaign following its launch. In July 2015, Ms. Kania shared her thoughts on the “JUUL brand evolution” with the Chief Marketing Officer and a creative consultant for the company: “[S]tay premium = yes, stay approachable = yes, fun = think we need to de-emphasize, as we’re getting more than a little flack for youthfulness and i [sic] think that as [sic] much to do with a playful tone as anything.”⁵⁴⁶ When asked in an interview with Subcommittee staff about these remarks, Ms. Kania described ongoing conversations among the JUUL board and employees about the public perception of the youthfulness of the Vaporized campaign and the company “missing the mark” in its efforts to target existing smokers.⁵⁴⁷

JUUL referred to the youthful nature of the campaign in the year after launch. For example, a February 2016 document describing “post launch insights” stated that “[t]he models that we used for the #Vaporized campaign appeared to be too youthful for

⁵⁴¹ JLI-PSI-00029687.

⁵⁴² Kania Interview (Nov. 15, 2019). According to a statement JUUL submitted in response to interrogatories from the Federal Trade Commission, as of October 2018, Ms. Kania was “the person at the Company most knowledgeable about JUUL Labs’ advertising, marketing, and promotional activities from January 1, 2015, to the present.” JLI-PSI-00450926.

⁵⁴³ JLI-PSI-00032444.

⁵⁴⁴ JLI-PSI-00141582.

⁵⁴⁵ *Id.*

⁵⁴⁶ JLI-PSI-00039914.

⁵⁴⁷ Kania Interview (Nov. 15, 2019).

many consumers (and the media).⁵⁴⁸ Similarly, the then-Chief Marketing Officer wrote in a March 2016 email to a JUUL board member that “post-launch feedback” included “[u]nwanted and unintended youthful positioning: models, colors and animations.”⁵⁴⁹

2. Negative Feedback from the Vaporized Campaign Eventually Lead JUUL to Rebrand

In response to negative feedback concerning the youthfulness of the Vaporized campaign, JUUL began a rebranding process. According to an internal document, JUUL was “horrified” by the reaction to the Vaporized campaign and “within [the] first 6 months of launch began to aggressively address” concerns with a “brand refresh nationwide.”⁵⁵⁰

The company acknowledged it “need[ed] to be sensitive to the subjectivity of youthfulness by positioning the brand to be mature and relatable.”⁵⁵¹ One step was to focus not only on the actual age of JUUL models but also the perceived age of models.⁵⁵² As JUUL learned, “[p]erception weighs as importantly as [the] letter of [the] law when it comes to [marketing] asset reviews.”⁵⁵³ JUUL also moved away from the bright colors it used in the Vaporized campaign and toward more muted tones of blue and green.⁵⁵⁴ JUUL’s 2016 rebrand guide described one objective of the rebrand campaign as “[r]etain[ing] brand recognition by relating to the original colors and imagery but using a refined aesthetic to appeal to c-store and vape shop consumers.”⁵⁵⁵

⁵⁴⁸ JLI-PSI-00143974.

⁵⁴⁹ JLI-PSI-00143985.

⁵⁵⁰ JLI-PSI-00433844.

⁵⁵¹ JLI-PSI-00143979. A settlement with Philip Morris for allegedly infringing Marlboro’s “roof design” trade dress also prohibited JUUL from using the triangles and diamond shapes from the Vaporized campaign. See Joint Stipulation for Dismissal of Entire Action with Prejudice, Pax Labs, Inc. v. Philip Morris USA, Inc. (N.D. Cal. Nov. 12, 2015) (No. 3:15-cv-03766). An August 2016 board meeting presentation stated, “Due to requirements outlined [in the] [Philip Morris International] settlement, we removed all JUUL branding that uses triangles and diamond shapes.” JLI-PSI-00127788. JUUL replaced the triangle and diamond shapes with a hexagon shape. JLI-PSI-00143976.

⁵⁵² JLI-PSI-00433844.

⁵⁵³ *Id.*

⁵⁵⁴ See, e.g., JLI-PSI-00143979.

⁵⁵⁵ *Id.*



Figure 16: JUUL Vaporized 2015 Colors and Imagery (Left) Compared to Rebranded Colors and Imagery (Right)⁵⁵⁶

The company also discussed and instituted marketing policies that suggested JUUL recognized how previous elements of its launch campaign promoted youth interest. In a December 2016 email, for example, Ms. Kania highlighted the need to move away from the heavily criticized youthful aspects of JUUL’s prior marketing campaign:

1. Models clearly aged 40+ according to 90% of adult viewers[;]
2. Color palette considered mature/not youthful according to 90% of adult viewers - and no colors that could be considered primary within the palette[;]
3. Final creative doesn’t exhibit sex appeal/make JUUL look sexy according to 90% of adult viewers[; and]
4. Generally doesn’t read as being geared towards under 21 audience, according to 90% of adult viewers[.]⁵⁵⁷

Ms. Kania’s ideas ultimately served as the cornerstone for an internal document titled, “Legal & Compliance Guidance,” which does not appear to have existed prior to January 2017.⁵⁵⁸ The guidance, which described JUUL’s values to third parties working with the company on brand development, emphasized that “marketing and positioning is intended and resonant with adults, not youth.”⁵⁵⁹ The guidance included the “direction” that the “[t]one and visual of brand does not appeal to children/youth”⁵⁶⁰ and described the “parameters” for this direction, including:

⁵⁵⁶ *Id.*

⁵⁵⁷ JLI-PSI-00141536. When asked about the color palette, Ms. Kania explained that she did not have a “silver bullet” definition for a mature color palette. She based her concern about primary colors on feedback the company received about the connection between bright colors and youthfulness of the Vaporized campaign. Kania Interview (Nov. 15, 2019).

⁵⁵⁸ *Cf.* JLI-PSI-00141536.

⁵⁵⁹ Kania Interview (Nov. 15, 2019); JLI-PSI-00143795.

⁵⁶⁰ JLI-PSI-00143795.

- no primary colors in palette
- no slang
- graphic treatment isn't juvenile or trendy
- no romance or sex appeal.⁵⁶¹

The company also stopped marketing JUUL products as “cool”—one of the cornerstones of JUUL’s Vaporized campaign.⁵⁶² In an email from October 2017, for example, a Senior Search Engine Optimization Lead provided feedback regarding proposed content for bloggers partnering with JUUL: “We can’t say ‘cool,’ interesting or chic would be ok.”⁵⁶³ In the company’s later campaign featuring testimonials from users who switched to JUUL from cigarettes, a guidance document for testimonial participants specifically prohibited references to JUUL being “cool.”⁵⁶⁴ A June 28, 2018, presentation by Deutsch, a company JUUL hired to organize a strategic response to youth usage, similarly stated: “We Need to Un-Cool Juul. To Put the Brand Narrative Back in Your Hands.”⁵⁶⁵ The “JUUL Brandbook 2018” also instructed internal marketing teams and external parties working on JUUL marketing campaigns to “[a]void using social popularity words,” listing “cool,” “fun,” “trendy,” “fashionable,” and “chic” as particular “words to avoid.”⁵⁶⁶

3. JUUL Attempted to Remove Vaporized Imagery

Even after these rebranding efforts, JUUL continued to receive complaints about the Vaporized campaign materials. In August 2018, when The Washington Post published an article referencing a JUUL advertisement with “a young woman in a bomber jacket and crop top,” the then-Chief Communications Officer asked other company employees if they knew the advertisement the article referenced.⁵⁶⁷ Ms. Kania responded: “I think I know the image he’s referring to – it’s from the 2015 launch campaign.”⁵⁶⁸ The Social Media Manager at the time added: “That campaign will haunt us forever.”⁵⁶⁹

Company employees, therefore, attempted to remove traces of Vaporized-related imagery online. In a February 13, 2018, email to the then-Director of Risk Mitigation, Compliance & Brand Protection, Ms. Henderson wrote: “There’s a 2-year-old ad that pops up on Google that displays a very youthful, ponytail and Letterman jacket-wearing ‘girl’ advertising JUUL. Is there any way we can get that removed/taken down?”⁵⁷⁰ In an interview with Subcommittee staff, Ms. Henderson stated that this advertisement

⁵⁶¹ *Id.*

⁵⁶² JLI-PSI-00046945.

⁵⁶³ JLI-PSI-00099114.

⁵⁶⁴ JLI-PSI-00115160.

⁵⁶⁵ Hong Interview (Nov. 20, 2019); JLI-PSI-00022029–30.

⁵⁶⁶ JLI-PSI-00143654.

⁵⁶⁷ JLI-PSI-00141243.

⁵⁶⁸ *Id.*

⁵⁶⁹ *Id.*

⁵⁷⁰ JLI-PSI-00076643.

bothered her, particularly the model's ponytail and the letterman jacket, styles that could conceivably be worn by high school students.⁵⁷¹ She also stated that she requested the removal of this advertisement because it "was not who JUUL is."⁵⁷²

JUUL was not successful in convincing Google to remove images of the advertisement.⁵⁷³ In late February 2018, JUUL Brand Protection "submitted a report to Google for copyright infringement to have the old JUUL marketing images displaying youthful users and diamond shaped devices removed."⁵⁷⁴ Google, however, "push[ed] back" on this request, arguing that the images fell under the "'fair use' exemption of copyright law."⁵⁷⁵ In a briefing to the Subcommittee, Google representatives explained that JUUL's removal request concerned images associated with third-party commentary critical of the Vaporized campaign; Google decided not to remove the content because nothing illegal had occurred in connection with these images.⁵⁷⁶

Unable to remove Vaporized images from Google, JUUL employees discussed "replacing" or "burying" these images by promoting current marketing advertisements and images. In an April 2018 email chain, an affiliate contractor wrote: "Even though erasing [the images] from the web is hard, I feel [it] could be worthwhile to do some 'reputation' work to show the current company approach."⁵⁷⁷ In response, the then-Vice President of Digital wrote: "A more pressing [search engine optimization] initiative should be to push the newest content to the top of image search and try to remove/replace images being pulled from old peices [sic]."⁵⁷⁸ Although the affiliate contractor continued to push to create new content, the then-Head of Experiential Marketing stressed that JUUL had released a number of images in recent years and asked: "[Why] can't [you] bury [the Vaporized images] with any of the stuff we've done in the past 2.5 years?"⁵⁷⁹ As with its attempts to remove images, JUUL's efforts to replace or bury images were unsuccessful; a simple Google search for "JUUL ads" continues to display images from the Vaporized campaign.

⁵⁷¹ Henderson Interview (Nov. 22, 2019).

⁵⁷² *Id.*

⁵⁷³ *Id.*

⁵⁷⁴ JLI-PSI-00140702.

⁵⁷⁵ *Id.*

⁵⁷⁶ Briefing with Google (May 12, 2020).

⁵⁷⁷ JLI-PSI-00124945.

⁵⁷⁸ *Id.*

⁵⁷⁹ JLI-PSI-00124944.

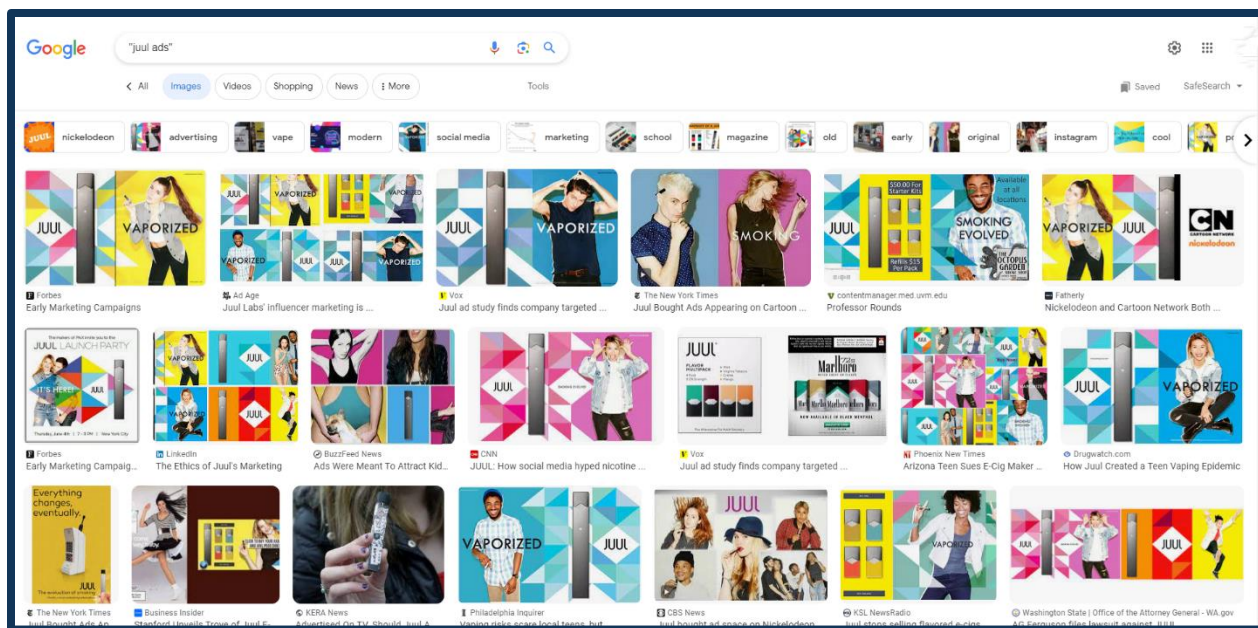


Figure 17: Screenshot of Google Images Results for an October 2023 “JUUL ads” Search⁵⁸⁰

4. Despite Its Efforts, JUUL Continued to Resonate with Youth

JUUL’s attempts to separate itself from the 2015 Vaporized campaign fell short and, years later, the product continued to resonate with youth. As part of its youth prevention efforts discussed more below, JUUL convened a “Youth Advisory Council” in August 2018, in which the company surveyed approximately one dozen individuals aged 21 and older to understand JUUL’s appeal among youth.⁵⁸¹ As detailed in a presentation summarizing the results of the council, participants had observed JUUL use among middle school and high school students and stated that JUUL continued to be “[p]opular among younger kids” generally.⁵⁸² Council participants also noted several factors contributing to underage JUUL use, including convenience, the lack of a need for youth “to febreze themselves before they saw their parents,” peer pressure, “[s]ocial acceptability and becoming a part of the ‘in crowd,’” and a desire “to feel older and more mature.”⁵⁸³

When asked for their impressions of the intended target audience for JUUL products, council participants cited a variety of ages, including “[s]ophomores in high school to 30 year olds,” “[j]uniors and seniors in high school,” and “[h]igh school and middle school students, minors in general.”⁵⁸⁴ One participant felt the targeted age was

⁵⁸⁰ Image results for “JUUL ads,” GOOGLE, <https://www.google.com/search?q=JUUL+ads> (last searched Oct. 25, 2023).

⁵⁸¹ JLI-PSI-00157771; JLI-PSI-00157955–64; Henderson Interview (Nov. 22, 2019).

⁵⁸² JLI-PSI-00157771; JLI-PSI-00157955.

⁵⁸³ JLI-PSI-00157771; JLI-PSI-00157959–60; JLI-PSI-00157963.

⁵⁸⁴ JLI-PSI-00157961.

“16 year olds, not intentionally,” and added, “but JUUL doesn’t care.”⁵⁸⁵ Similarly, another stated: “Maybe not intentionally but the marketing is towards young people and the high school kids will notice that the older kids are doing it and it makes them want to do it.”⁵⁸⁶

Finally, council participants also pointed to specific dangers associated with the branding and marketing of JUUL products. One participant, for example, stated that “[t]he company markets towards young kids. Similar marketing to iPhone. Skinny, small, rechargeable, portable and very addictive to kids.”⁵⁸⁷ Others noted that “[a]ds with young adults using JUUL will attract kids” and “impressionable kids will use it if they see their peers or people they look up to using it.”⁵⁸⁸ Similarly, one participant explained the difficulty of “draw[ing] the line with what kind of young person [JUUL was] marketing towards,” and stated it was “hard to distinguish marketing between 16-21 year olds.”⁵⁸⁹

As noted above, Ms. Henderson informed Subcommittee staff that she shared results from the council with Ms. Gould, but she was not aware of further efforts by the company to address the findings.⁵⁹⁰ Because the focus group occurred around the time when JUUL ended its broader youth prevention efforts, Ms. Henderson did not believe Ms. Gould or other executives acted on the information.⁵⁹¹

B. JUUL Knew Social Media Activity Contributed to Its Popularity Among Underage Users but Struggled to Curb Youth-Related Social Media Activity Related to Its Products

JUUL recognized that social media activity played an important role in promoting the popularity of JUUL products among underage users. Through tracking, JUUL was aware that youth followed its social media accounts and were among its most loyal followers. JUUL, however, struggled to combat this phenomenon.

1. JUUL Tracked Its Youth and Young Adult Social Media Followers

In terms of its company-run social media pages, JUUL was aware that youth and young adults were among its “[s]trong[ly] engaged” and “loyal” followers.⁵⁹² For example, among JUUL’s Twitter account followers, nearly one-fifth of followers were aged 13 to 17; nearly half were aged 18 to 24.⁵⁹³ JUUL’s 10,042 followers on Instagram also included a number of individuals aged 13 to 17, despite the largest percentage being aged 18 to 34.⁵⁹⁴ According to a May 2018 internal document, “[m]ost

⁵⁸⁵ *Id.*

⁵⁸⁶ *Id.*

⁵⁸⁷ JLI-PSI-00157955.

⁵⁸⁸ *Id.*; JLI-PSI-00157963.

⁵⁸⁹ JLI-PSI-00157959.

⁵⁹⁰ Henderson Interview (Nov. 22, 2019).

⁵⁹¹ *Id.*

⁵⁹² JLI-PSI-00166119.

⁵⁹³ JLI-PSI-00352539.

⁵⁹⁴ JLI-PSI-00352538.

significantly, the 13-17 age group account[ed] for 7.0% of the audience on Instagram.”⁵⁹⁵ The document warned that “[i]t will be important to monitor this audience shift over time.”⁵⁹⁶

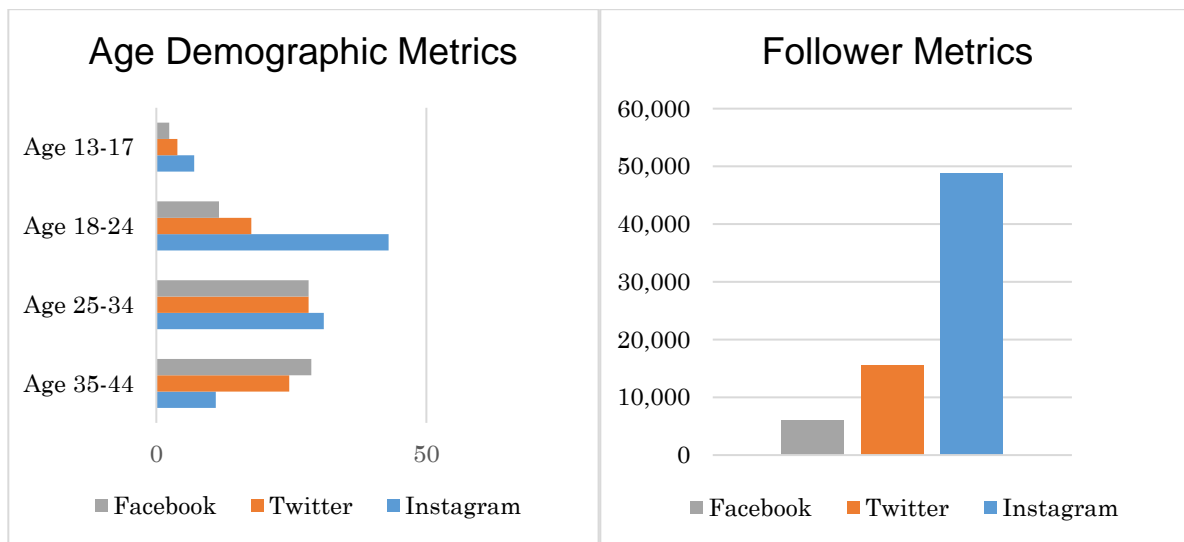


Figure 18: JUUL Social Media Metrics in May 2018⁵⁹⁷

2. JUUL Was Aware that Social Media Contributed to Youth Popularity

Employees recognized how social media contributed to the products’ popularity among youth. A Senior Manager for health education in the Education & Youth Prevention department, for example, wrote in June 2018: “[w]e’re aware of the animosity [toward JUUL] and understand that it’s due to the product’s popularity among youth which we believe grew, in great part, as a result of its prolific presence on social media.”⁵⁹⁸ Ms. Henderson explained in an interview with Subcommittee staff that she learned shortly after joining the company in 2018 that youth were using social media to “market” JUUL products to each other.⁵⁹⁹ She further stated that “the JUUL team as a whole . . . were all surprised at the social media phenomenon.”⁶⁰⁰

Around the same time, a social media audit conducted for JUUL concluded that Instagram “fan pages that are run by those of vaping age demonstrate a brand loyalty and viral quality that no other vape brand possesses. This is a huge advantage, but

⁵⁹⁵ JLI-PSI-00239107. The report also suggests that JUUL did not start tracking the 13-to-17 year-old age group prior to March 2018 for Facebook and Twitter and May 2018 for Instagram. *Id.* One study found that almost half of JUUL’s Twitter followers in April 2018 were youth and young adults. Out of the 9,077 individual followers, researchers estimated that 80.6 percent were between ages 13 and 20, and 19.4 percent were age 21 or older. Annice Kim et al., *Estimated Ages of JUUL Twitter Followers*, 173 JAMA PEDIATRICS 690, 691 (2019).

⁵⁹⁶ JLI-PSI-00239107.

⁵⁹⁷ *Id.*

⁵⁹⁸ JLI-PSI-00154737.

⁵⁹⁹ Henderson Interview (Nov. 22, 2019).

⁶⁰⁰ *Id.*

should be monitored closely as there is also a huge community of underage users running fan & meme pages about JUULing.”⁶⁰¹ Similarly, in July 2018, a Strategy and Business Operations employee flagged “a potential rising trend on YouTube among youth called ‘JUUL sesh,’ which [was] short for JUUL session,” stating: “My main concern, beyond the obvious usage, is the uniformity of the video title and the purpose of the video, which can have a viral effect.”⁶⁰²

Participants in the 2018 JUUL “Youth Advisory Council” also noted the prominent role of social media activity in encouraging underage JUUL use. For example, one participant mentioned being “[i]ntroduced to Juul by a younger crowd on social media, this is coming from a 20-something.”⁶⁰³ Other participants mentioned the “[c]ool factor to it” and the fact that “[p]opular social media influencers tell their followers to use JUUL,” as well as “[m]emes about JUUL.”⁶⁰⁴

3. JUUL Struggled to Curb Youth-Related Social Media Content

Despite JUUL’s understanding of the important role of social media in its popularity among youth, JUUL struggled to address content related to youth use on social media platforms for several reasons, including alleged resistance from social media platforms, limited staff, and difficulty blocking underage users from viewing its content. An email from a Brand Protection Online Enforcement Analyst in August 2018, for example, stated that based on a review of weekly statistics, “one of the most glaring results was the noticeably small enforcement numbers sent out for Social Media.”⁶⁰⁵ An audit JUUL commissioned from a third party on the company’s presence on social media platforms also noted that weaknesses associated with JUUL’s Instagram account included “[l]ess effort shown to combat underage use until April 24th, 2018.”⁶⁰⁶

Alleged Resistance by Social Media Platforms. When JUUL did take enforcement efforts on social media, JUUL accused social media platforms, including Instagram and YouTube, of hampering its efforts. According to a February 2018 email from Bruce Harter, a consultant for the Education & Youth Prevention department, “Instagram has only been marginally cooperative and JUUL is attempting to set up a meeting with high enough level Instagram staff to make the case that Instagram needs to monitor pictures that glamorize products that are unlawful and addictive to teens.”⁶⁰⁷ Mr. Harter also noted that YouTube had been slightly more cooperative, “remov[ing]

⁶⁰¹ JLI-PSI-00166122.

⁶⁰² JLI-PSI-00283530. As noted below in more detail, YouTube representatives stated in a briefing to the Subcommittee that, in general, a video of an underage individual simply using JUUL was not then a violation of YouTube Community Guidelines. Briefing with Google (May 12, 2020). In subsequent follow-up to the Subcommittee, Google clarified that “prohibition of content on YouTube involving minors using controlled substances – including vaping, alcohol, nicotine, and e-cigarettes – has been in place for years, and was effective at the time of our briefing to Subcommittee staff.” Email from Google to the Subcommittee (Feb. 22, 2024).

⁶⁰³ JLI-PSI-00157771; JLI-PSI-00157955.

⁶⁰⁴ JLI-PSI-00157957; JLI-PSI-00157959.

⁶⁰⁵ JLI-PSI-00013350.

⁶⁰⁶ JLI-PSI-00166119.

⁶⁰⁷ JLI-PSI-00069461.

underage videos of JUUL use,” although it still failed to “take[] responsibility to monitor and remove.”⁶⁰⁸ Other employees, however, had differing views, with one JUUL employee describing YouTube as “the least compliant social media platform in terms of removing content” as of July 2018.⁶⁰⁹ A 2018 internal “regulatory update” noted that “[c]urrently, Social Media platforms have informed us that they will only remove postings only if they are selling JUUL products but will not remove posting even if they include company copyright material and/or trademarks.”⁶¹⁰ Similarly, Ms. Henderson explained to a concerned pediatrician in 2018 that JUUL’s takedown efforts “had little to no success with Snapchat, Instagram, Redditt [sic] and others who argue that such take-downs would violate first amendment rights.”⁶¹¹

In briefings to the Subcommittee, representatives from Instagram, Twitter, and Google explained that, in general, the companies did not remove organic (or non-advertising) content that might feature underage use of vaping products generally or JUUL products specifically.⁶¹² Representatives from YouTube, a Google subsidiary, did, however, note that the company had instituted guidelines to remove videos featuring youth participating in the “JUUL Challenge,” in which individuals attempted to vape as much as possible during a particular period of time.⁶¹³ YouTube also age restricted videos of adults participating in the challenge.⁶¹⁴ According to the briefing from YouTube in 2020, a video of an underage individual simply using JUUL did not violate YouTube Community Guidelines.⁶¹⁵ More than three years later, in subsequent follow-up to the Subcommittee, Google clarified that “prohibition of content on YouTube involving minors using controlled substances – including vaping, alcohol, nicotine, and

⁶⁰⁸ *Id.*

⁶⁰⁹ JLI-PSI-00283530. In contrast to JUUL’s experience with social media platforms, the company appears to have had success reporting infringing listings or accounts reselling JUUL products to online sales platforms. In a May 2018 email, for example, Ms. Henderson explained: “We’ve become fairly successful in getting e-Bay [sic] and Amazon to remove most of their postings. . . . Most of our success has been with e-commerce sites for removing ads for potential sales.” JLI-PSI-00003103. As of April 2018, JUUL had known that eBay was “a very easy platform to buy and sell without age verification for the JUUL device. Because teens are extremely tech savvy, it takes little effort to purchase a JUUL Underage [sic].” JLI-PSI-00125894.

⁶¹⁰ JLI-PSI-00027271.

⁶¹¹ JLI-PSI-00003103.

⁶¹² Briefing with Instagram (Apr. 17, 2020); Briefing with Twitter (Apr. 24, 2020); Briefing with Google (May 12, 2020).

⁶¹³ Briefing with Google (May 12, 2020).

⁶¹⁴ *Id.*

⁶¹⁵ *Id.* A Google representative also explained that YouTube policies generally do not prohibit videos depicting underage use of other regulated substances like tobacco and alcohol. However, the company will remove videos of “extremely dangerous challenges” involving regulated substances—similar to the “JUUL Challenge”—that may endanger underage individuals. YouTube policies also require the removal of videos that attempt to sell or promote regulated goods—through links on videos or seller contact information, for example. Email from Google to the Subcommittee (May 27, 2020). In subsequent follow-up to the Subcommittee, Google clarified that “prohibition of content on YouTube involving minors using controlled substances – including vaping, alcohol, nicotine, and e-cigarettes – has been in place for years, and was effective at the time of our briefing to Subcommittee staff.” Email from Google to the Subcommittee (Feb. 22, 2024).

e-cigarettes – has been in place for years, and was effective at the time of our briefing to Subcommittee staff.”⁶¹⁶

Representatives from all three companies also noted that JUUL’s removal requests generally either failed to state a trademark or copyright violation or did not include actionable information. A YouTube representative, for example, explained that a JUUL logo simply appearing in a video did not constitute a copyright violation, and footage of JUUL use alone did not amount to a trademark violation.⁶¹⁷ Twitter representatives stated that JUUL sent the company 11 letters between April 2018 and April 2020, many of which simply reported organic content that involved discussions of JUUL products or mentions of the company, neither of which constituted a trademark violation.⁶¹⁸ A true trademark violation for Twitter, by contrast, would involve an individual employing the JUUL trademark in a way that misleads or confuses other users about the individual’s affiliation with the company.⁶¹⁹ Twitter took action in only 20 out of 475 unique cases of potential trademark infringement JUUL reported in 2019.⁶²⁰ Similarly, an Instagram representative recalled a letter from JUUL in which the company reported the total number of posts it had identified as violating Instagram policies but did not provide actionable information.⁶²¹ Instagram later stated that certain “intellectual property reports by JUUL were non-actionable because the content in question—for example, the use of the term ‘JUUL’ to refer to JUUL’s own products, or depicting people using those products—did not appear to violate [the company’s] trademark policy.”⁶²²

Personnel Limitations. Compounding these difficulties, JUUL faced personnel limitations that impacted its social media enforcement efforts. Ms. Henderson explained to Subcommittee staff that when she joined the company in early 2018, JUUL had only two employees responsible for searching social media and requesting removal of problematic content.⁶²³ She stated that then-CEO Burns called for expanding resources dedicated to this effort; he allegedly noted that his former company, yogurt manufacturer Chobani, had five employees searching social media—and, in contrast to e-cigarettes, “no one cared about yogurt.”⁶²⁴ In addition, the JUUL employees responsible for social media enforcement efforts seemed to have lacked the training necessary for submitting actionable reports to social media platforms. For example, a Twitter representative found it “very concerning” that the reports the company received from JUUL did not state clear or specific policy violations.⁶²⁵

⁶¹⁶ Email from Google to the Subcommittee (Feb. 22, 2024).

⁶¹⁷ Briefing with Google (May 12, 2020).

⁶¹⁸ Briefing with Twitter (Apr. 24, 2020).

⁶¹⁹ *Id.*

⁶²⁰ *Id.*

⁶²¹ Briefing with Instagram (Apr. 17, 2020).

⁶²² Email from Facebook to the Subcommittee (May 22, 2020). An Instagram representative also informed the Subcommittee that the company has “taken down content reported by JUUL when they have submitted complete and valid reports demonstrating the reported content violates their intellectual property, including, for example, attempts to market or sell counterfeit JUUL products.” *Id.*

⁶²³ Henderson Interview (Nov. 22, 2019).

⁶²⁴ *Id.*

⁶²⁵ Briefing with Twitter (Apr. 24, 2020).

Technical Limitations in Removing Underage Followers. JUUL also encountered technical limitations on its ability to police followers of company accounts. Although the company implemented an age gate on its Instagram account in July 2018—prohibiting individuals under the age of 21 from accessing the account—according to internal correspondence, JUUL could only remove followers “to the extent [it] ha[d] age information based on matched Facebook accounts.”⁶²⁶ Employees warned, “Please bear in mind that we don’t have perfect or complete information and the gate is not a guarantee—for example, a follower with an unconfirmed or unknown age won’t be removed (or blocked) from the account.”⁶²⁷ As the then-Social Media Manager explained:

[A] user has to agree that they are over the age of 21 before they can view our page and content. The age gate here is optics based - a follower can agree that they are over 21 if they are not and still view our account, the same as they would on our website. Our team therefore manually reviews all followers added and if any are clearly underage we block them.⁶²⁸

In any event, correspondence from December 2017 shows that company employees engaged in blocking underage Instagram followers on a daily basis.⁶²⁹ Moreover, after the social media audit noted above suggested that “[w]ith a very young demographic using Instagram, JUUL’s profile could benefit from additional educational content on the addictive properties of nicotine,” the company did, in fact, post this content.⁶³⁰ In addition, JUUL policies included a general prohibition on interacting with “any JUUL fan accounts or communities that appeal to underage users.”⁶³¹ A summary of the JUUL social media code from October 2018 demonstrates increased restrictions from the company on its social media accounts.⁶³² These restrictions included limiting access to its Instagram and YouTube accounts for users under the age of 18, restricting access to its Facebook accounts for users under the age of 21, and blocking or declining to engage with anyone under 18 on Twitter.⁶³³

C. JUUL Knew Youth Subverted the Website’s Age Verification Controls but Failed to Sufficiently Strengthen Those Controls

Beginning in 2015, JUUL contracted with Veratad for age verification services, ensuring that those purchasing products off the JUUL website were of legal age. Veratad matched personal identifying information of prospective JUUL purchasers against individuals of legal age in its database.⁶³⁴ A user who failed this initial check

⁶²⁶ JLI-PSI-00098943.

⁶²⁷ *Id.*

⁶²⁸ JLI-PSI-00141249.

⁶²⁹ JLI-PSI-00375224.

⁶³⁰ JLI-PSI-00166122; Kania Interview (Nov. 15, 2019); JLI-PSI-00371075 (“Every post includes nicotine warning: WARNING: This product contains nicotine. Nicotine is an addictive chemical.”).

⁶³¹ JLI-PSI-00371075.

⁶³² *Id.*

⁶³³ *Id.*

⁶³⁴ Massachusetts Complaint, *supra* note 450.

could submit an “alternate” address, the last four digits of his or her Social Security number, or government-issued photo identification to assist with verification.⁶³⁵ Starting in August 2017, JUUL used “ID match and age verification technology on [its] website to ensure that customers attempting to purchase on JUUL.com are age 21+, while the legal age of purchase in many states is 18.”⁶³⁶ According to Ms. Henderson, during the time of her interview with the Subcommittee in 2019, age verification efforts involved a five-step process that required a phone number or utility bill to verify the age of a user and his or her length of residence.⁶³⁷ She added that the company continued to develop new techniques for blocking underage sales, educating retailers, and tracking JUUL devices.⁶³⁸

Despite these efforts, company documents describe significant problems with youth subverting these controls. In March 2017, for example, a Customer Services Manager noted that an underage user was “able to order by changing the name of his billing address to an adults [sic] name and still continue to ship to himself.”⁶³⁹ Moreover, an internal company presentation stated in November 2017 that for online purchases of JUUL products, “[w]e do not always require an ID upload” and “ID [u]pload isn’t foolproof – customers can photoshop to bypass this step.”⁶⁴⁰

Statistics from the JUUL age verification system indicated that a significant percentage of attempted buyers on its website were potentially underage. A January 2018 email from a Veratad representative stated that the daily JUUL “pass rate”—the rate at which potential purchasers verified their identity—was only 68 to 72 percent for JUUL, as opposed to 90 to 95 percent for JUUL’s sister company Pax Labs.⁶⁴¹ According to the representative, “[t]his indicates that JUUL has 1.) a younger more transient demographic 2.) potentially more underage users trying to purchase product 3.) less users are willing to upload and 4.) [they] are entering data not as accurately as PAX users.”⁶⁴² He also stated:

I don’t believe that we’ve ever truly uncovered why only about 50% of users who failed the data process upload a document. Of course this could be because the users that decline to upload are kids or fraudsters, but if at all possible, I would like to work with you to try and figure that out.⁶⁴³

Third parties repeatedly alerted the company of the need to improve its age verification measures. A “concerned parent,” for example, asked JUUL in February 2018 to “look into making your age verification systems a little more robust” because “[a]nyone underage can apparently place orders using only the name of an individual 21

⁶³⁵ *Id.*

⁶³⁶ JLI-PSI-00027271. See also JLI-PSI-00060819; JLI-PSI-00124808; JLI-PSI-00135901.

⁶³⁷ Henderson Interview (Nov. 22, 2019).

⁶³⁸ *Id.*

⁶³⁹ JLI-PSI-00131419.

⁶⁴⁰ JLI-PSI-00069660.

⁶⁴¹ JLI-PSI-00150340.

⁶⁴² *Id.*

⁶⁴³ *Id.*

years or older.”⁶⁴⁴ She further stated that by explaining on the JUUL website that “the age verification system uses only public records to verify whether or not an individual is at least 21,” the company “essentially informs minors how to place orders, simply by using the name of someone who is at least 21.”⁶⁴⁵ Dr. Jackler also wrote to Ms. Henderson “to suggest that your IT team look into the fact that rejected under age purchasers are subscribed to JUUL’s marketing emails,” as well as the fact that “under age individuals can sign up for [JUUL’s] newsletter.”⁶⁴⁶

Participants in the 2018 “Youth Advisory Council” also confirmed the ease with which certain underage users could order JUUL products from the company website. One participant, for example, noted that you can “[o]rder [JUUL products] online, verification is simple. Super easy and discreet to get them online.”⁶⁴⁷ Another participant recommended “[s]tricter verification online” because “kids send JUULs to Amazon lockers so they don’t need to show ID.”⁶⁴⁸ In fact, a report memorializing a September 2018 FDA inspection of JUUL headquarters stated that from a review of a sample of youth-related complaints, 10 of 19 complaints “were associated with minors using fraudulent IDs to purchase or obtain replacement products.”⁶⁴⁹ According to the FDA report, JUUL acknowledged flaws in its verification systems that allowed minors to receive its products.⁶⁵⁰ For example, the company “reported that minors may be able to obtain product replacements and warranty replacements via the complaint department by using an adult’s identification and account created through their online purchases.”⁶⁵¹

JUUL, nevertheless, failed to strengthen its age verification systems in a timely manner, thereby allowing youth to continue to access its products. An email from January 2018, for example, suggests JUUL had failed to implement sufficient fraud detection tools.⁶⁵² An employee from an age verification vendor wrote that his company had “numerous fraud detection services that are being used by big tobacco [sic] that you guys [at JUUL] currently are not leveraging.”⁶⁵³ Further, at least one employee expressed a desire for JUUL to avoid proactively investigating potentially underage accounts registered with the company. In October 2017, a Fraud Analyst reported that he had discovered “over 80 accounts” associated with an e-mail domain for a high school in Florida and proposed that “someone should take a look at these accounts and decide if we need to block any more.”⁶⁵⁴ In response, a Customer Support Manager wrote: “Certainly, [we] want to block people that are underage, I think we can all agree

⁶⁴⁴ JLI-PSI-00004905.

⁶⁴⁵ *Id.*

⁶⁴⁶ JLI-PSI-00005900.

⁶⁴⁷ JLI-PSI-00157957.

⁶⁴⁸ *Id.*

⁶⁴⁹ FDAPSI1150719–83.

⁶⁵⁰ *Id.*

⁶⁵¹ FDAPSI1150719–81. According to the report, JUUL later “updated their processes and procedures to ensure age verification is completed before any shipment of product and warranty replacements.” *Id.*

⁶⁵² JLI-PSI-00150339.

⁶⁵³ *Id.*

⁶⁵⁴ JLI-PSI-00121051.

on that. I want support [personnel] to be a partner to flag people that we know are underage. However, I want to avoid them digging around looking for it.”⁶⁵⁵

D. JUUL Did Not Undertake Robust Efforts to Understand or Prevent Social Sourcing

JUUL was also aware that “social sourcing”—in which legal users purchased and then re-sold, gifted, or otherwise distributed JUUL products to youth—contributed to youth use. Ms. Henderson described social sourcing as one of the company’s “biggest challenges.”⁶⁵⁶ She added:

Most kids are getting JUULs from older friends who can purchase legally. They’re also accessing through gray market sales (people who legally buy several start-up packets at a local vape shop then market to kids on Snapchat or Instagram). We send these dealers’ postings to local law enforcement as soon as we learn about them which isn’t quickly enough yet.⁶⁵⁷

Mr. Harter provided anecdotal evidence about the social sourcing phenomenon following a visit he made to a high school: “Eighteen year olds are buying multiple JUUL starter kits and selling them at a huge mark-up to middle school and younger high school students.”⁶⁵⁸ Based on statistics from an outside organization, Ms. Henderson estimated that “[k]ids [got] JUUL . . . 52% from social sources” as of June 2018.⁶⁵⁹ In an interview with Subcommittee staff, Ms. Henderson also described recent middle school use of JUUL products as a social sourcing issue.⁶⁶⁰

Comments JUUL received from the “Youth Advisory Council” in August 2018 highlighted the social sourcing issue.⁶⁶¹ One participant explained, for example, that JUUL products were “[v]ery popular in New York City high schools. A lot of kids are buying JUULs wholesale and dealing them at their high schools.”⁶⁶² Similarly, another participant stated that “[b]uying JUUL and reselling is very popular at the high school level,” and a third stated that “[my] [y]ounger brother asks me to buy him JUUL pods constantly. Kids pay older students to buy it for them.”⁶⁶³ In addition to these findings, Ms. Henderson told Subcommittee staff that they regularly raised social sourcing in meetings with educators and on the youth prevention hotline.⁶⁶⁴

According to Ms. Henderson, JUUL executives briefly discussed finding studies on social sourcing to help them understand the phenomenon, and she wanted to

⁶⁵⁵ *Id.*

⁶⁵⁶ JLI-PSI-00152557.

⁶⁵⁷ JLI-PSI-00152895.

⁶⁵⁸ JLI-PSI-00152940.

⁶⁵⁹ JLI-PSI-00152213.

⁶⁶⁰ Henderson Interview (Nov. 22, 2019).

⁶⁶¹ See JLI-PSI-00157955–64.

⁶⁶² JLI-PSI-00157957.

⁶⁶³ *Id.*

⁶⁶⁴ Henderson Interview (Nov. 22, 2019).

conduct her own research as well.⁶⁶⁵ Such efforts, however, were paused by the summer of 2018, when the company closed its Education & Youth Prevention department.⁶⁶⁶ The company took no other efforts to develop solutions to social sourcing.⁶⁶⁷

V. JUUL'S YOUTH PREVENTION EFFORTS MIRRORED TOBACCO INDUSTRY TECHNIQUES AND MAY HAVE MISLED SCHOOLS

As reports of youth use of JUUL increased, the company recognized this was “a problem”⁶⁶⁸ and launched mitigation efforts. JUUL established an Education & Youth Prevention department in early 2018 to educate youth, parents, and teachers on the dangers of nicotine through a vaping-related curriculum and partnerships with schools and local youth organizations. In seeking a clean break from the legacy of the tobacco industry, however, the company overlooked lessons that could have helped it avoid encouraging youth use. Specifically, before launching its efforts, the company failed to research similar programs led by the tobacco industry. As a result, JUUL was unaware that leading anti-tobacco organizations had criticized similar initiatives as “ineffective at best” and had warned that they “can even work to encourage kids to smoke.”⁶⁶⁹ The lack of due diligence JUUL performed before launching its youth prevention activities prevented the company from fully realizing the potential of these efforts. After criticism comparing its efforts to those of the traditional tobacco industry, JUUL disbanded its Education & Youth Prevention department and stopped all outreach and education efforts by the fall of 2018—after less than a full year in operation.⁶⁷⁰

Troublingly, JUUL also promoted its youth prevention efforts by overselling the feasibility of anti-vaping technology to schools desperate to curb youth use. Mr. Harter even implied that JUUL might withhold access to “beacon” technology that would detect and deactivate JUUL products “if JUUL [was] not allowed to work with schools.”⁶⁷¹ He internally explained that the “beacon is the door opener for conversations with school staff. . . . [W]ithout the promise of the beacon [JUUL] won’t get a listen.”⁶⁷² Around this time, however, the Vice President of Engineering wrote that “it’s unclear . . . if effective vape detectors are real,” and JUUL executives “tabled” discussion and development of anti-vaping technology.

A. JUUL's Youth Prevention Efforts

In January 2018, JUUL created an Education & Youth Prevention department—consisting of Ms. Henderson as director, three employees, and two consultants—to

⁶⁶⁵ *Id.*

⁶⁶⁶ *Id.*

⁶⁶⁷ *Id.*

⁶⁶⁸ *Id.*

⁶⁶⁹ JLI-PSI-00024637–38.

⁶⁷⁰ A JUUL representative stated to the Subcommittee in October 2020 that the company did not intend to restart its youth outreach and education efforts. Briefing with JUUL Labs, Inc. (Oct. 2, 2020).

⁶⁷¹ JLI-PSI-00069071.

⁶⁷² JLI-PSI-00155843.

combat and prevent youth use of its products.⁶⁷³ Ms. Henderson told Subcommittee staff that when she discussed her potential employment with JUUL, executives acknowledged youth use as a problem the company wanted to address.⁶⁷⁴ The goal of the Education & Youth Prevention department was to partner with schools and other organizations to educate youth, parents, and teachers about the dangers of nicotine.

Youth Prevention Outreach to Schools. The department's primary efforts centered on building relationships with schools. JUUL conducted community conversations with educators and parents to inform them about the vaping industry, ways to identify signs of youth use, and how to talk to youth about nicotine.⁶⁷⁵ The main targets—over 95 percent—were schools identified in media reports as having issues with underage JUUL use.⁶⁷⁶ The remaining five percent of JUUL's targets were California schools known to the two consultants working for the Education & Youth Prevention department.⁶⁷⁷ By April 2018, the Education & Youth Prevention department “contacted more than 300 [school] districts, individual schools, police activities leagues, health organizations and prevention agencies.”⁶⁷⁸ When asked about the general reception from schools, Ms. Henderson said the response varied, but most schools were skeptical because of previous manipulative efforts from the private sector.⁶⁷⁹

Youth Prevention Curricula. When JUUL reached out to schools regarding its youth prevention efforts, it primarily offered a “Moving Beyond E-Cigarettes & Marijuana” intervention curriculum.⁶⁸⁰ Designed for grades 9 through 12, the curriculum spanned three sessions and focused on “the underlying science that demonstrate [sic] the dangers of e-cigarette and marijuana use for teenagers, the social influences that teens must address, and the use of mindful practices that provide students with an alternative to using e-cigarettes and marijuana.”⁶⁸¹ Mr. Harter assembled the curriculum from public sources, including the Stanford Medical School (related to the science of vaping), the National Institutes of Health (“NIH”), and Harvard University (related to mindfulness).⁶⁸² Mr. Burns and Ms. Gould reviewed and approved this curriculum.⁶⁸³ Ultimately, JUUL shared the curriculum with at least twelve and as many as two dozen schools.⁶⁸⁴ To Ms. Henderson's knowledge, the only school system that used any part of the curriculum was Agua Fria Union High School District in Arizona.⁶⁸⁵

⁶⁷³ JLI-PSI-00249616; JLI-PSI-00002820.

⁶⁷⁴ Henderson Interview (Nov. 22, 2019).

⁶⁷⁵ *Id.*; JLI-PSI-00002820.

⁶⁷⁶ Henderson Interview (Nov. 22, 2019).

⁶⁷⁷ *Id.*

⁶⁷⁸ *Id.*; JLI-PSI-00152709.

⁶⁷⁹ Henderson Interview (Nov. 22, 2019).

⁶⁸⁰ *Id.*

⁶⁸¹ JLI-PSI-00040976.

⁶⁸² See JLI-PSI-00024361; JLI-PSI-00040976; JLI-PSI-00040988; JLI-PSI-00040995; JLI-PSI-00041002; JLI-PSI-00041005.

⁶⁸³ Henderson Interview (Nov. 22, 2019).

⁶⁸⁴ *Id.*

⁶⁸⁵ *Id.*

Separately, in the spring of 2018, JUUL began developing a prevention curriculum that focused on grades 6 through 12, with the goal of leading students to their own decision that vaping products were not appropriate to use.⁶⁸⁶ At the time, according to Ms. Henderson, there was no model for a prevention curriculum for vaping and no related resources—with the exception of Stanford’s Tobacco Prevention Toolkit.⁶⁸⁷ JUUL worked with teachers and an educational organization to draft the prevention curriculum using an interdisciplinary approach involving math, social studies, and English to help students develop arguments based on evidence.⁶⁸⁸ The curriculum, however, “never saw the light of day.”⁶⁸⁹ Ms. Henderson told Subcommittee staff that during the drafting stage of the prevention curriculum in April or May 2018, she was occupied with meetings with school officials across the country and had little time to focus on the curriculum.⁶⁹⁰ Although she intended to revisit the curriculum over the summer, the company decided to wind down its youth prevention efforts by June 2018, and JUUL senior leadership therefore directed Ms. Henderson to hold off on this initiative.⁶⁹¹ She did not recall when or why the company decided to end its curriculum development, but she added that JUUL employees felt misunderstood and frustrated with media portrayals that depicted the company’s youth prevention efforts as ineffective and potentially encouraging e-cigarette use among youth.⁶⁹²

Youth Prevention Agreements with Schools. JUUL entered into formal agreements with three charter schools and school districts on youth prevention efforts: Freedom and Democracy Public Charter Schools, Agua Fria Union High School District, and Hinsdale Township High School District.⁶⁹³ Ms. Henderson informed Subcommittee staff that only these three schools wanted to partner with the company.⁶⁹⁴ The agreements provided that each school would receive a grant to aid schools in implementing its intervention curriculum in any Saturday school program, in-school program, or summer school program.⁶⁹⁵ School staff ran these programs.⁶⁹⁶ The agreements required only that the schools provide JUUL with the dates and times of the program, the number of students who attended each program, and evaluation and assessment forms from participants.⁶⁹⁷

⁶⁸⁶ *Id.*; JLI-PSI-00152709.

⁶⁸⁷ Henderson Interview (Nov. 22, 2019).

⁶⁸⁸ *Id.*

⁶⁸⁹ *Id.*

⁶⁹⁰ *Id.*

⁶⁹¹ *Id.*

⁶⁹² *Id.*

⁶⁹³ JLI-PSI-00146580–83; JLI-PSI-00003688–92; JLI-PSI-00069481–85.

⁶⁹⁴ Henderson Interview (Nov. 22, 2019).

⁶⁹⁵ The agreements called for a \$10,000 grant, which JUUL calculated based on the cost of holding Saturday school in California. JLI-PSI-00146580–81; JLI-PSI-00003688–90; JLI-PSI-00069481–82. JUUL entered into a separate agreement with Freedom and Democracy Public Charter Schools for a “Healthy Life Adventures Summer Pilot.” JUUL agreed to provide \$154,000 to help students in grades 3 through 12 “create a personal ‘healthy lifestyle plan’ by exposing and engaging low-income youth at risk of making poor health decision to a vast array of positive life experiences, healthy alternatives to risky behaviors, and structured, student-led inquiry (with teacher facilitation) of beneficial lifestyle practices.” JLI-PSI-00002791–94.

⁶⁹⁶ JLI-PSI-00003688–89.

⁶⁹⁷ JLI-PSI-00146581; JLI-PSI-00003689–90; JLI-PSI-00069482.

JUUL did not ultimately receive information from schools on how they spent the grant money and the company never formally audited these agreements.⁶⁹⁸ Ms. Henderson believed the only instance in which schools utilized the intervention curriculum was in a freshmen orientation at an Agua Fria high school.⁶⁹⁹ In addition, the company never received information from schools on the number of student participants or any evaluations and assessments.

Partnerships with Other Youth-Oriented Organizations. JUUL also conducted outreach to professional trade groups, parent teacher associations (“PTAs”), school resource officers, teacher groups, and Police Activities Leagues (“PALs”) to educate these organizations about the vaping industry and explore potential partnerships to benefit local communities.⁷⁰⁰ JUUL attended the national PALs conference and supported PALs programming with youth, which included police officers mentoring children with life skills courses and recreational activities.⁷⁰¹ Ms. Henderson noted that JUUL was also uninvited from a PTA conference because PTAs saw JUUL as part of the tobacco industry.⁷⁰² JUUL reached out to around a dozen organizations in total prior to ending its community engagement efforts; it is no longer conducting outreach.⁷⁰³

Similar to its engagement with school districts, the company entered into agreements with certain youth-oriented organizations, including the Richmond PAL, Black Mental Health Alliance, Steve’s Camp at Horizon Farms, LifeSkills, Inc., and Impact Canine Solutions.⁷⁰⁴ In total, JUUL agreed to pay over \$500,000 to these organizations.⁷⁰⁵ According to Ms. Henderson, the purpose of these agreements was to identify successful youth prevention services that educated youth on the dangers of substance abuse and promoted healthy lifestyles to help JUUL scale up its prevention efforts.⁷⁰⁶ She added that JUUL was “grasping at straws.”⁷⁰⁷

Distribution of Materials. Separate from the curricula and partnerships discussed above, JUUL distributed resources to parents during community conversations or when concerned parents emailed JUUL’s youth prevention hotline—youthprevention@JUUL.com.⁷⁰⁸ Mr. Harter took the lead in compiling these materials, which included a document titled, “Talking to Teens About E-cigarettes,” as well as

⁶⁹⁸ Henderson Interview (Nov. 22, 2019). Ms. Henderson informed the Subcommittee that she believed Mr. Harter visited the Agua Fria program on at least one occasion. *Id.*

⁶⁹⁹ *Id.*

⁷⁰⁰ *Id.*; JLI-PSI-00006888–89; JLI-PSI-00152709.

⁷⁰¹ Henderson Interview (Nov. 22, 2019).

⁷⁰² *Id.*

⁷⁰³ *Id.*

⁷⁰⁴ JLI-PSI-00024120–24; JLI-PSI-00009661–62; JLI-PSI-00052216–20; JLI-PSI-00003324–26; JLI-PSI-00024221–25; JLI-PSI-00152200–10.

⁷⁰⁵ JLI-PSI-00024120–24; JLI-PSI-00009661–62; JLI-PSI-00052216–20; JLI-PSI-00003324–26; JLI-PSI-00024221–25; JLI-PSI-00152200–10.

⁷⁰⁶ Henderson Interview (Nov. 22, 2019).

⁷⁰⁷ *Id.*

⁷⁰⁸ See, e.g., JLI-PSI-00068711; JLI-PSI-00006695.

publicly available material from the U.S. Surgeon General, CDC, and NIH.⁷⁰⁹ JUUL stopped distributing materials to parents around the spring or summer of 2018.⁷¹⁰

B. JUUL Failed to Research Prior Tobacco Industry Outreach Before Launching Its Youth Prevention Efforts

Prior to launching the education and youth prevention efforts described above, JUUL failed to research similar efforts the tobacco industry had used to attract youth and young adult users.⁷¹¹ Ms. Henderson was unaware of JUUL conducting any such research prior to her joining the company in January 2018.⁷¹² After her arrival, Ms. Henderson waited months before conducting any research into tobacco industry youth prevention efforts to ensure JUUL did not repeat these techniques.⁷¹³ Ms. Henderson acknowledged to Subcommittee staff that she should have familiarized herself with this history earlier, but her focus was on developing and implementing the youth prevention efforts discussed above.⁷¹⁴ Ms. Henderson also explained that she was new to the industry, had never worked in a corporate setting before, and needed time to learn the culture of JUUL.⁷¹⁵

Comparisons between JUUL and tobacco industry youth outreach efforts started in early 2018 and originated from external sources, including the media, government agencies, and non-profit organizations.⁷¹⁶ In March 2018, for example, the Washington State Department of Health emailed an alert to Washington schools, writing: “JUUL is providing funds and programming to schools. The tobacco industry has a long history of sponsoring youth prevention programming that ultimately undermine evidence-based tobacco control efforts, and JUUL is no different.”⁷¹⁷ The department further recommended that “schools/districts reject these offers.”⁷¹⁸ The CATCH Global Foundation similarly issued an alert after learning that JUUL was approaching schools: “Tobacco industry-made youth programs have historically been ineffective at best and might even encourage tobacco use.”⁷¹⁹ The Campaign for Tobacco-Free Kids and the Youth Engagement Alliance for Tobacco Control also issued a warning encouraging schools to reject JUUL’s program, comparing the company’s efforts to previous

⁷⁰⁹ JLI-PSI-00030920–32.

⁷¹⁰ Henderson Interview (Nov. 22, 2019). Other JUUL youth prevention initiatives, not necessarily in the purview of the Education & Youth Prevention department, included: age and ID verification online; social media monitoring and underage content removal; investigating and policing retailer compliance; and joining the WeCard program. JLI-PSI-00002820; JLI-PSI-00155688.

⁷¹¹ Henderson Interview (Nov. 22, 2019).

⁷¹² *Id.*

⁷¹³ *Id.* Ms. Henderson also did not research efforts by other industries, despite one colleague recommending that she review youth prevention efforts by the alcohol industry for “interesting points / lessons” and to “benchmark against [JUUL’s] proposed tactics.” JLI-PSI-00006941–43.

⁷¹⁴ Henderson Interview (Nov. 22, 2019).

⁷¹⁵ *Id.*

⁷¹⁶ *Id.*

⁷¹⁷ JLI-PSI-00002839.

⁷¹⁸ *Id.*; JLI-PSI-00176464–65.

⁷¹⁹ JLI-PSI-00155747–49.

initiatives from tobacco companies.⁷²⁰ The organization cautioned that “[p]arents and teachers shouldn’t get advice about e-cigarettes from companies that make and profit from e-cigarettes”:

There is a reason to be cautious about JUUL’s efforts. Tobacco companies have an extensive history of promoting prevention programs that studies have shown to be ineffective at best and can even work to encourage kids to smoke. While JUUL Labs is not one of the Big Tobacco companies, it is still a tobacco company selling an addictive product that has significant youth appeal and they should not be partnering with schools.⁷²¹

Only after four months at JUUL, in April 2018, did Ms. Henderson review tobacco industry youth outreach efforts. In an April 16, 2018, email, Ms. Henderson wrote that she researched these programs “[a]fter so many comments comparing us to big tobacco [sic].”⁷²² She wanted to understand why JUUL was being painted “with the broad strokes of Big Tobacco.”⁷²³ Ms. Henderson reviewed primary sources, internal communications, and summaries of documents from the DOJ suit against major tobacco companies, the Truth Tobacco Industry Documents archive at the University of California San Francisco (“UCSF”), and publicly available documents in UCSF’s online collection from the tobacco litigation.⁷²⁴

Ms. Henderson compiled a chart summarizing her findings of the similarities between JUUL’s youth prevention efforts and tobacco industry programs from 1980 through 2000.⁷²⁵ The chart documented significant similarities between JUUL and the tobacco industry. For example, Ms. Henderson identified comparisons between JUUL’s intervention curriculum and the tobacco industry’s “Right Decisions, Right Now” curriculum campaign, which was a free educational tobacco prevention program.⁷²⁶ Similarly, Ms. Henderson found the tobacco industry’s “Helping Youth Decide” and “Helping Youth Say No” programs to be similar to JUUL’s community conversations and town hall meetings with parents and educators.⁷²⁷ The chart also reflected the involvement of both JUUL and the tobacco industry in the WeCard program,⁷²⁸ and that both had conducted outreach to youth-focused third parties, such as the Boys & Girls Clubs.⁷²⁹

⁷²⁰ JLI-PSI-00024637–38.

⁷²¹ *Id.*

⁷²² JLI-PSI-00167058.

⁷²³ Henderson Interview (Nov. 22, 2019).

⁷²⁴ *Id.*; JLI-PSI-00167058.

⁷²⁵ JLI-PSI-00166903–06.

⁷²⁶ JLI-PSI-00166903. See RIGHT DECISIONS RIGHT NOW, *About the Program*, <https://www.rightdecisionsrightnow.com/about-the-program> (last visited Jan. 26, 2024).

⁷²⁷ JLI-PSI-00166904. Although not indicated on the chart, JUUL also provided parents with materials titled, “Talking to Teens About E-cigarettes.” JLI-PSI-00030920–28.

⁷²⁸ JLI-PSI-00166904. The We Card program includes educational and training services to help retailers identify and prevent underage attempts to purchase age-restricted products, including tobacco, alcohol, e-cigarettes, and other vapor products. WE CARD, *About Us*, <https://www.wecard.org/about-us> (last visited Jan. 26, 2024).

⁷²⁹ JLI-PSI-00166905–06; Henderson Interview (Nov. 22, 2019).

YOUTH PREVENTION PROGRAMS by Type and Purpose

Type of Program	Name of JUUL's Program	Intended Purpose(s)	Possible Misinterpretations	Big Tobacco - sponsored Programs (1980 - 2000)
Youth Education	Introductory Intervention Curriculum Pilot (Intro - 3 hr pilot)	Educate youth of the health affects of nicotine on the developing adolescent brain & body;	Generates good PR; Builds alliances w/educators & school law enforcement;	"Right Decisions, Right Now" (RJR, 1991) "Juveniles Should Not Smoke" (Finland, 1992)
	HS & MS Intervention Curricula (10-21 hr ELA units)	Provide self-efficacy strategies for addressing peer influences	Marginalizes extant health education and abuse prevention educational programs;	"Smoking Can Wait" (Russia, 1994-1995)
	Prevention Curricula Grades 6-12 10-22 hr units embedded in ELA/SS	Provide non-substance alternatives to addressing teen stresses	De-rails regulation	MTV Campaign
	PSAs - media campaigns (incl social media)	<i>Identify & replicate/scale most effective prevention program(s) & approaches; Ultimate goal is to reduce youth use down to below the lowest levels of youth smokers</i>	Collects data on youth for marketing purposes	

Figure 19: Chart Comparing JUUL and Tobacco Industry “Youth Education” Programs⁷³⁰

After conducting this research, Ms. Henderson wanted JUUL to pause and strategize how it would address the comparisons she discovered.⁷³¹

C. Comparisons to the Tobacco Industry’s Youth Outreach Led JUUL to Discontinue Its Youth Prevention Program

JUUL executives did not discuss the tobacco industry’s youth outreach efforts until after Ms. Henderson’s research in April 2018.⁷³² Ms. Henderson recalled that she did not have an immediate discussion about her comparison chart with Mr. Burns or Ms. Gould but instead had general, piecemeal conversations about the importance of the company understanding the comparisons to the tobacco industry and being aware of the issues.⁷³³ Ms. Henderson, however, could not recall a meeting during which employees discussed definitive next steps, and the company never formulated a strategic plan on how to distinguish its youth prevention efforts from those of the

⁷³⁰ JLI-PSI-00166903. In her interview with Subcommittee staff, Ms. Henderson expressed her disappointment in the findings compiled in the chart, explaining that the tobacco industry “smoke screen[ed] everybody” by creating materials that teachers desperately needed and then using these materials as marketing tools. Henderson Interview (Nov. 22, 2019).

⁷³¹ Henderson Interview (Nov. 22, 2019). When asked about the investment of tobacco company Altria in JUUL, Ms. Henderson said she was disturbed by the investment because Altria is “Big Tobacco.” She believed Altria was hedging its bets through its investment—looking for ways to “contain the beast that threatens their existence.” *Id.*

⁷³² *Id.*

⁷³³ *Id.*

tobacco industry.⁷³⁴ As a result, JUUL never settled on a “silver bullet” solution or a specific date for implementation.⁷³⁵

Nevertheless, Ms. Henderson implemented certain changes to JUUL’s youth prevention efforts. Ms. Henderson told Subcommittee staff that her biggest suggestion after compiling the chart was for JUUL to relinquish any control or influence over the relationships it maintained with schools and provide them complete autonomy.⁷³⁶ As mentioned above, the agreements between the company and schools required the schools to provide JUUL with data on attendance and participants’ evaluations and assessments.⁷³⁷ JUUL amended the contracts so that schools could use any curricula and included this parameter in other discussions and contract negotiations.⁷³⁸ Further, JUUL stopped attending certain community events, such as student health fairs. As Ms. Henderson explained to Mr. Harter in April 2018:

Just spoke w/ Ashley [Gould] & she shares my concern about the optics of us attending a student health fair given our new understanding of how much our efforts seem to duplicate those of big tobacco [sic] (Philip Morris attended fairs and carnivals where they distributed various branded items under the guise of ‘youth prevention’).⁷³⁹

Around the same time, in May 2018, Ms. Gould received scientific papers and articles on the tobacco industry’s youth outreach, including the “paper that ended the Think Don’t Smoke campaign undertaken by Phillip [sic] Morris,”⁷⁴⁰ from a public health professor at New York University. Ms. Gould set up a call between the professor and Ms. Henderson “to discuss what the industry lived through with PMI [Philip Morris International] . . . as well as stepping back and thinking through this with an understanding of what happened before and considerations for what will be best to prevent youth usage on the educational side.”⁷⁴¹ Ms. Henderson later spoke with the professor, who proposed ending JUUL’s youth prevention program altogether.⁷⁴² According to Ms. Henderson, the professor felt JUUL’s youth prevention efforts had been misunderstood and distracted from the company’s mission.⁷⁴³

Following Ms. Henderson’s research and the professor’s suggestion, JUUL executives began reconsidering its youth prevention efforts.⁷⁴⁴ In a May 23, 2018, email to the Education & Youth Prevention department consultants, Ms. Henderson wrote:

⁷³⁴ *Id.*

⁷³⁵ *Id.*

⁷³⁶ *Id.*

⁷³⁷ See, e.g., JLI-PSI-00003688–92.

⁷³⁸ Henderson Interview (Nov. 22, 2019).

⁷³⁹ JLI-PSI-00027104.

⁷⁴⁰ JLI-PSI-00156190–269.

⁷⁴¹ JLI-PSI-00123487.

⁷⁴² Henderson Interview (Nov. 22, 2019).

⁷⁴³ *Id.*

⁷⁴⁴ *Id.*

Ashley [Gould] has requested that we hold off on any new outreach efforts to schools. This came after a meeting she had with a [New York University] professor who's supportive of JUUL's efforts to eliminate cigarettes but against our [Youth Prevention] programs & efforts because of Big Tobacco's use of education as a marketing tool. The professor/advisor argues that we could potentially harm JUUL's future as a company because our ed programs are being viewed, confused & conflated with those employed by Big Tobacco.⁷⁴⁵

At that time, the Education & Youth Prevention department had contacted around 360 schools.⁷⁴⁶

The company never restarted outreach to schools and promotion of the youth prevention curricula after this time, and JUUL began to wind down the initiatives of the Education & Youth Prevention department by June 2018.⁷⁴⁷ As a Senior Director of Communications wrote: "We received negative feedback from schools -- Big Tobacco -- we were frankly unaware. We are evaluating what is an appropriate thing for JUUL to be part of with respect to education and curriculum. We are NOT reaching out to schools. We will help if they want it."⁷⁴⁸ JUUL ultimately disbanded the Education & Youth Prevention department in August or September 2018.⁷⁴⁹

D. JUUL Representatives Oversold the Feasibility of Anti-Vaping Technology

As part of its youth prevention efforts, JUUL sought to develop a potential technological innovation described as a "beacon device for schools."⁷⁵⁰ This "stealth" device would resemble a smoke detector or water sprinkler and alert school officials when a student used a JUUL device on campus.⁷⁵¹ The beacon would also deactivate the e-cigarette, which only the company's online age verification process could reactivate.⁷⁵² In early 2018, members of the Education & Youth Prevention department began advertising the device in their outreach to schools about the company's youth prevention program—despite the beacon still being in development.⁷⁵³ Mr. Harter even appeared to suggest that access to the beacon technology was limited to schools participating in the company's youth program. In a February 7, 2018, email Mr. Harter wrote:

⁷⁴⁵ JLI-PSI-00123484–85.

⁷⁴⁶ Henderson Interview (Nov. 22, 2019).

⁷⁴⁷ *Id.*

⁷⁴⁸ JLI-PSI-00161732.

⁷⁴⁹ Henderson Interview (Nov. 22, 2019). A JUUL representative confirmed in October 2020 that the company had not revived its education and youth prevention efforts, in part because other entities were in a better position to conduct this outreach. Briefing with JUUL Labs, Inc. (Oct. 2, 2020).

⁷⁵⁰ JLI-PSI-00067650.

⁷⁵¹ JLI-PSI-00041009.

⁷⁵² *Id.*

⁷⁵³ Henderson Interview (Nov. 22, 2019).

[B]y the end of next month, JUUL will be piloting a device that will not only disable JUUL products in schools but also notify the administrators where and when they are being used. . . . California Schools will lose two significant interventions if JUUL is not allowed to work with schools. . . . Second, the opportunity to have JUUL install devices that will disable JUULs in schools.⁷⁵⁴

Throughout the spring of 2018, JUUL continued to advertise the beacon to school officials, who responded enthusiastically.⁷⁵⁵ In an email with the subject “[Youth Prevention] Update for week of 3/12/18,” Ms. Henderson wrote under “[f]ield meetings this past week”:

[A]dministrators & [School Resource Officers] – desperate for stealth beacon . . . Per meetings with administrators, SROs – All are interested & wish to purchase the stealth beacon (e.g., in addition to [Oklahoma], schools in Tempe, Phoenix, Notre Dame Private School in Sherman Oaks (CA), Hinsdale, IL) – all want to install the beacon ASAP.⁷⁵⁶

JUUL, however, oversold the availability of the beacon. In reality, the device was still in development and not ready to be piloted by March 2018; this estimate was “wishful thinking.”⁷⁵⁷ By the spring of 2018, in fact, the company was still looking for functional vape detectors to test. In an April 2018 email with the subject, “what vape detectors are actually out there,” the Vice President of Engineering wrote: “Right now it’s unclear to me if effective vape detectors are real (I hope they are, sounds like a great part of the youth prevention toolbox!).”⁷⁵⁸ He directed Ms. Henderson to reach out to a vape detector company that had appeared in media articles in the hope that the company would let JUUL test its device.⁷⁵⁹ Ms. Henderson told Subcommittee staff that she was not presented with any research that showed this particular device was effective.⁷⁶⁰

By May 2018, schools were requesting more information on the device. In a May 5, 2018, email, Mr. Harter wrote that JUUL had “reached a turning point on the beacon” and “need[ed] the go-ahead from Ashley [Gould] and/or Kevin [Burns] as well as more information on the technical side.”⁷⁶¹ Ms. Henderson told Subcommittee staff that she believed the “turning point” referred to requests from school officials for more

⁷⁵⁴ JLI-PSI-00069071. When asked about Mr. Harter’s email, Ms. Henderson explained that she did not believe Mr. Harter to be conditioning access to the beacon on the participation of schools in JUUL’s youth prevention efforts. She added that she “cannot imagine” Mr. Harter doing so. Henderson Interview (Nov. 22, 2019).

⁷⁵⁵ Henderson Interview (Nov. 22, 2019).

⁷⁵⁶ JLI-PSI-00004258.

⁷⁵⁷ Henderson Interview (Nov. 22, 2019).

⁷⁵⁸ JLI-PSI-00153357.

⁷⁵⁹ *Id.*

⁷⁶⁰ Henderson Interview (Nov. 22, 2019).

⁷⁶¹ JLI-PSI-00153405.

specifications about the beacon, and the “go ahead” concerned the release date of the beacon.⁷⁶²

It was around this time, however, that JUUL “deprioritized” and tabled the development of the beacon.⁷⁶³ In a May 30, 2018, email, Ms. Henderson wrote:

Spoke briefly w/ [the Vice President of Engineering] today on this issue and he reiterated how senior management opted to take the beacon idea off the table indefinitely. He was also very adamant about us not talking about this item/option in any of our future presentations and/or meetings (and admonished me for discussing it in the past couple of meetings) because of sr. management’s decision which is based on the reasoning that: 1) kids could/would/might find a way to beat the beacon; and 2) that there isn’t a vape detector out there that really works.⁷⁶⁴

Ms. Henderson explained to Subcommittee staff that the company tabled the beacon because it questioned whether the device would actually reduce vaping.⁷⁶⁵ In addition, company engineers were preparing for the FDA PMTA process.⁷⁶⁶ One JUUL engineer also believed the JUUL vaping device had to pass the PMTA approval process first before the company could explore different iterations of the device, including a version that a beacon product could deactivate.⁷⁶⁷ Employees within the Education & Youth Prevention department disagreed with the decision to table the beacon because they believed the beacon was important to educators.⁷⁶⁸ For example, Mr. Harter responded to Ms. Henderson’s May 30, 2018, email stressing that the beacon was a “door opener” for JUUL and warning that, without the promise of the device, JUUL would not “get a listen” from schools.⁷⁶⁹ Ms. Henderson noted that the beacon was “back on the table” at JUUL as of September 2018 and told Subcommittee staff in November 2019 that it was a “very big priority” at the company.⁷⁷⁰

On July 30, 2020, JUUL submitted its PMTA for Tobacco and Menthol flavors at nicotine concentrations of 5 percent and 3 percent.⁷⁷¹ On June 23, 2022, FDA issued a marketing denial order (“MDO”) to JUUL for all their products currently marketed in the United States, and as a result, JUUL was ordered to stop selling and distributing these

⁷⁶² Henderson Interview (Nov. 22, 2019).

⁷⁶³ JLI-PSI-00155844.

⁷⁶⁴ JLI-PSI-00155843.

⁷⁶⁵ Henderson Interview (Nov. 22, 2019).

⁷⁶⁶ *Id.*

⁷⁶⁷ *Id.*

⁷⁶⁸ *Id.*; JLI-PSI-00155843.

⁷⁶⁹ JLI-PSI-00155843. When asked about this email in an interview with Subcommittee staff, Ms. Henderson did not agree with Mr. Harter that the beacon device was a “door opener.” She believed other aspects of the JUUL message and the company’s offer of support, generally, were more appealing. Henderson Interview (Nov. 22, 2019).

⁷⁷⁰ Henderson Interview (Nov. 22, 2019).

⁷⁷¹ Juul Labs, Inc., *JUUL Labs Submits Premarket Tobacco Product Application to the U.S. Food and Drug Administration for the JUUL System* (July 30, 2020), <https://www.juulabs.com/juul-labs-submits-premarket-tobacco-product-application/>.

products and to remove products currently on the market or risk enforcement action.⁷⁷² FDA determined that JUUL’s application “lacked sufficient evidence regarding the toxicological profile of the products to demonstrate that marketing of the products would be appropriate for the protection of the public health.”⁷⁷³ JUUL appealed FDA’s ruling and the U.S. Court of Appeals for the D.C. Circuit entered a temporary administrative stay of the MDO on June 24, 2022.⁷⁷⁴ On July 5, 2022, FDA administratively stayed the MDO after “determin[ing] that there are scientific issues unique to the JUUL application that warrant additional review” and the agency is conducting a secondary review of JUUL’s PMTA, which is still in progress.⁷⁷⁵

During FDA’s review process, JUUL has remained on the market. According to March 2023 convenience store data, JUUL’s market share was 26 percent, a steep decline from a 74 percent market share in May 2019.⁷⁷⁶ Despite its drop in market share, JUUL continues to press forward. In July 2023, JUUL submitted an application for its “next-generation” product—a Bluetooth-enabled device that is meant to lock out underage users and reject counterfeit pods.⁷⁷⁷ FDA has not ruled on this application.

⁷⁷² Press Release, U.S. Food & Drug Admin., FDA Denies Authorization to Market JUUL Products (June 23, 2022), <https://www.fda.gov/news-events/press-announcements/fda-denies-authorization-market-juul-products>.

⁷⁷³ *Id.*

⁷⁷⁴ *Id.*

⁷⁷⁵ *Id.* See also Jamie Ducharme, *I Wrote the Book On Juul in 2021. Here’s What’s Happened to the Vaping Industry Since*, TIME (Oct. 12, 2023), <https://time.com/6322368/what-happened-to-juul/>.

⁷⁷⁶ *Vuse Market Share Grows While Juul Drops*, TOBACCO REPORTER (Apr. 6, 2023), <https://tobaccoreporter.com/2023/04/06/vuse-market-share-grows-while-juul-drops/>.

⁷⁷⁷ Juul Labs, Inc., *A Technological Solution for Public-Health Problems: JUUL Labs Submits the First PMTA for its Next-Generation Platform to Improve Adult-Smoker Switching and Restrict Underage Access* (July 19, 2023), <https://www.juullabs.com/next-generation-platform-pmta/>.

PART IV: THE FEDERAL GOVERNMENT CONTINUED TO CHANGE E-CIGARETTE REGULATORY ENFORCEMENT DESPITE JUUL'S RISE AND THE YOUTH VAPING EPIDEMIC

After the effective date of the deeming rule, all deemed products were subject to Section 910 of the FD&C Act, which imposes certain premarket review requirements for tobacco products not commercially marketed in the United States before February 15, 2007.⁷⁷⁸ Accordingly, FDA required newly deemed tobacco products, including e-cigarettes, to obtain premarket authorization.⁷⁷⁹ As a result, any products remaining on the market without FDA authorization would be unlawful.⁷⁸⁰

When it published the deeming rule in 2016, FDA exercised its “discretion” and determined that newly deemed tobacco products would not “be subject to enforcement” during certain compliance periods established in the rule.⁷⁸¹ Specifically, the deeming rule “establish[ed] staggered initial compliance periods based on the expected complexity of the [PMTA] applications to be submitted, followed by continued compliance periods for FDA review,” with FDA’s “exercise of enforcement discretion [set to] end twelve months after each initial compliance period.”⁷⁸² The deeming rule, therefore, provided manufacturers of all newly deemed tobacco products with up to 24-months to prepare PMTAs after the effective date of the rule—or until November 8, 2018.⁷⁸³ Products could remain on the market during this period and up to another year pending FDA’s review.⁷⁸⁴ FDA established these specific compliance periods because it “determined that exercising enforcement discretion indefinitely could put youth and young adults at risk for tobacco-related death and disease.”⁷⁸⁵

Since finalizing the deeming rule and JUUL’s rise, the federal government has compounded problems with e-cigarette enforcement through multiple extensions of these compliance deadlines, which have allowed manufacturers like JUUL to continue selling their products with little oversight. Although the federal government indicated in September 2019 that it would ban all flavored e-cigarette products, this policy was never implemented. Instead, in January 2020, FDA announced that it would prioritize enforcement against certain flavored e-cigarette products and products targeted towards youth. Although a step in the right direction, FDA’s priorities did not account for all flavors and all types of e-cigarettes—allowing significant loopholes to remain.

⁷⁷⁸ Deeming Rule, 81 Fed. Reg. 28,974 at 28,976.

⁷⁷⁹ *Id.*

⁷⁸⁰ *Id.*

⁷⁸¹ *Id.* at 28,978.

⁷⁸² *Id.* at 28,977–78.

⁷⁸³ *Id.* at 28,978.

⁷⁸⁴ *Id.*

⁷⁸⁵ *Id.* at 28,977.

I. IN 2017, FDA EXTENDED COMPLIANCE DEADLINES FOR PRE-MARKET AUTHORIZATION, ALLOWING FLAVORED E-CIGARETTES TO STAY ON THE MARKET WITH MINIMAL OVERSIGHT

When Scott Gottlieb became FDA Commissioner in May 2017, FDA extended the compliance deadlines outlined in the deeming rule by three months.⁷⁸⁶ Mr. Zeller told the Subcommittee that he explained to Commissioner Gottlieb that e-cigarettes were an extremely divisive and emotional issue with “pitched camps diametrically opposed to one another.”⁷⁸⁷ Thus, Mr. Zeller recommended a comprehensive approach to nicotine that focused on a “continuum of risk” and sought to reduce nicotine levels and transition users to less harmful nicotine delivery mechanisms.⁷⁸⁸

According to Mr. Zeller, this approach ultimately led to FDA’s comprehensive tobacco plan published in August 2017 (“August 2017 Guidance”).⁷⁸⁹ As part of this plan, FDA further extended the PMTA submission deadlines such that manufacturers of e-cigarettes did not need to submit PMTAs until August 8, 2022.⁷⁹⁰ As noted above, the deeming rule originally set a deadline of August 8, 2018, for these PMTAs.⁷⁹¹ FDA also stated that it intended to defer enforcement until it rendered a decision on the relevant application, meaning that products could remain on the market for as long as FDA took to consider the application—more than just the 12-month period contained in the final rule.⁷⁹² The August 2017 Guidance explained that FDA had set compliance dates “as a matter of enforcement discretion” in an effort to “give industry more time to comply.”⁷⁹³ Mr. Turman described the August 2017 Guidance as a “fairly comprehensive plan” and stated that the extension was designed to give industry more time to understand the application process and review standards.⁷⁹⁴ He also believed this would prevent FDA from having to reject or delay a product intended to help users transition away from cigarettes for avoidable procedural reasons.⁷⁹⁵

FDA acknowledged that manufacturers would continue to market products when preparing their PMTAs and during the agency’s review.⁷⁹⁶ Mr. Zeller told the Subcommittee that FDA was aware of the popularity of e-cigarette products, but there

⁷⁸⁶ Three-Month Extension of Certain Tobacco Product Compliance Deadlines Related to the Final Deeming Rule: Guidance for Industry, 82 Fed. Reg. 22,338 (May 15, 2017).

⁷⁸⁷ Zeller Briefing (July 25, 2019).

⁷⁸⁸ *Id.*

⁷⁸⁹ CTR. FOR TOBACCO PRODS., U.S. FOOD & DRUG ADMIN., EXTENSION OF CERTAIN TOBACCO PRODUCT COMPLIANCE DEADLINES RELATED TO THE FINAL DEEMING RULE GUIDANCE FOR INDUSTRY (REVISED) (2017) [hereinafter 2017 GUIDANCE].

⁷⁹⁰ *Id.*

⁷⁹¹ Deeming Rule, 81 Fed. Reg. 28,974 at 28,978.

⁷⁹² 2017 GUIDANCE, *supra* note 789.

⁷⁹³ *Id.*

⁷⁹⁴ Turman Interview (Nov. 7, 2019).

⁷⁹⁵ *Id.*

⁷⁹⁶ Press Release, U.S. Food & Drug Admin., FDA Announces Comprehensive Regulatory Plan to Shift Trajectory of Tobacco-Related Disease, Death (July 27, 2017), <https://www.fda.gov/news-events/press-announcements/fda-announces-comprehensive-regulatory-plan-shift-trajectory-tobacco-related-disease-death>.

was a need for FDA to issue foundational rules, which was the reasoning for extending the PMTA application deadline.⁷⁹⁷ Further, the 2015 through 2017 NYTS results showed youth use of e-cigarettes declining or leveling off.⁷⁹⁸ Based on this and other available data, Mr. Zeller believed that FDA needed to take the time to create a comprehensive approach to tobacco products and that a four-year extension was an appropriate amount of time to allow FDA to issue guidance.⁷⁹⁹ He acknowledged that, in retrospect, if he had seen the 2018 NYTS, which covered 2017 data and showed an “alarming” rise in youth e-cigarette use, he would not have extended the application deadline to 2022.⁸⁰⁰

II. FDA MOVED UP THE COMPLIANCE DEADLINE AFTER BEING SUED FOR DELAYING E-CIGARETTE ENFORCEMENT AND RECEIVING ADDITIONAL DATA ON YOUTH E-CIGARETTE USE

In March 2018, the American Academy of Pediatrics (“AAP”) challenged the August 2017 Guidance in the U.S. District Court for the District of Maryland.⁸⁰¹ AAP argued, in part, that FDA did not develop the August 2017 Guidance in accordance with notice and comment requirements under the Administrative Procedure Act.⁸⁰² On May 15, 2019, the court agreed and vacated the August 2017 Guidance, writing:

As noted, youth use of e-cigarettes has reached epidemic proportions. The FDA recognizes this and professes to be “deeply concerned about the risks that e-cigarettes pose for children, given how quickly teenage use of these products has accelerated.” It also “believe[s] e-cigarettes can be an important off-ramp for adults who are addicted to combustible cigarettes,” but asserts that “[t]he technology that might help adults end one addiction cannot [be permitted to] pull a generation of kids into a new one.”⁸⁰³

The District Court criticized FDA’s decision to issue the August 2017 Guidance, contrasting the concerns FDA had expressed with the slow pace of its enforcement.⁸⁰⁴ In the court’s view, the guidance was a “decision to hold in abeyance” enforcement of a statutory mandate “Congress viewed as integral to address public health dangers that the agency itself acknowledges are alarming for five or more years . . . all the while affording those manufacturers responsible for the public harm a holiday from meeting the obligations of the law.”⁸⁰⁵

⁷⁹⁷ Zeller Briefing (July 25, 2019). According to FDA, “FDA could not regulate e-cigarettes as tobacco products until the foundational deeming rule was final and in effect.” Email from HHS to the Subcommittee (Feb. 22, 2024)

⁷⁹⁸ *Id.*

⁷⁹⁹ *Id.*

⁸⁰⁰ *Id.*

⁸⁰¹ *Am. Acad. of Pediatrics v. Food & Drug Admin.*, 379 F. Supp. 3d 461, 496 (D. Md. 2019).

⁸⁰² *Id.*

⁸⁰³ *Id.* at 473.

⁸⁰⁴ *Id.*

⁸⁰⁵ *Id.*

While this litigation was pending, in August 2018, FDA received preliminary data from the 2018 NYTS, which showed an alarming increase in youth e-cigarette use.⁸⁰⁶ FDA “was surprised” at the spike in youth use, given that it had seen a “two-year period of decline and leveling off of youth use of e-cigarettes.”⁸⁰⁷ But the increase led to then-Commissioner Gottlieb declaring youth e-cigarette use an “epidemic”:

[D]espite our progress, and these metrics, we find ourselves at a very challenging crossroads in the execution of this plan. That’s because we didn’t foresee the extent of what’s now become one of our biggest challenges. We didn’t predict what I now believe is an epidemic of e-cigarette use among teenagers. Today we can see that this epidemic of addiction was emerging when we first announced our plan last summer. Hindsight, and the data now available to us, reveal these trends. And the impact is clearly apparent to the FDA. Unfortunately, I now have good reason to believe that it’s reached nothing short of an epidemic proportion of growth.⁸⁰⁸

The same day, in a separate statement regarding FDA enforcement actions related to the sale and marketing of e-cigarettes to youth, Commissioner Gottlieb explained he believed “certain flavors are one of the principal drivers of the youth appeal of these products.”⁸⁰⁹ Several months later, on March 20, 2019, Commissioner Gottlieb and HHS Secretary Alex Azar authored an op-ed in *The Washington Post* that stated e-cigarette use increased by “nearly 80 percent” among high-school-age teens and by “nearly 50%” among middle-school-age children.⁸¹⁰ They acknowledged that “FDA had not accurately anticipated the upsurge in e-cigarette use by the young,” and they attributed these concerning results, in part, to the “e-cigarette industry’s slowness to address the dangers its products pose to teens.”⁸¹¹

According to Mr. Zeller, his presentation of the alarming 2018 NYTS data to Commissioner Gottlieb and reports about youth use of JUUL led FDA to reconsider its August 2017 Guidance.⁸¹² FDA issued its “Modifications to Compliance Policy for Certain Deemed Tobacco Products” in March 2019 (“March 2019 Draft Guidance”), which proposed moving the PMTA deadline for certain flavored e-cigarettes to August 8,

⁸⁰⁶ Zeller Briefing (July 25, 2019).

⁸⁰⁷ Zeller Interview (July 2, 2020).

⁸⁰⁸ Statement, U.S. Food & Drug Admin., Statement from FDA Commissioner Scott Gottlieb, M.D., on New Steps to Address Epidemic of Youth E-Cigarette Use (Sept. 11, 2018), <https://www.fda.gov/news-events/press-announcements/statement-fda-commissioner-scott-gottlieb-md-new-steps-address-epidemic-youth-e-cigarette-use>.

⁸⁰⁹ *Id.*

⁸¹⁰ Alex Azar & Scott Gottlieb, Op-Ed, *The Future of E-Cigarettes Depends on the Industry’s Willingness to Protect Teens*, WASH. POST (Mar. 20, 2019), <https://www.washingtonpost.com/opinions/2019/03/19/future-e-cigarettes-depends-industrys-willingness-protect-teens/?noredirect=on>.

⁸¹¹ *Id.*

⁸¹² Zeller Briefing (July 25, 2019).

2021—a year sooner than in the August 2017 Guidance.⁸¹³ FDA would still allow products, including flavored products, to remain on the market until the agency made a decision on each application.⁸¹⁴ In developing this standard, FDA found that “[m]any [e-cigarette] products are being marketed to minors through a wide variety of media,” including television, radio, and social media.⁸¹⁵ FDA also cited examples of “appealing cartoons as well as the use of minors or people who appear to be minors in multimedia advertisements” and referenced previous descriptions of nicotine products resembling juice boxes, candy, and kid-friendly cereal.⁸¹⁶ Commissioner Gottlieb’s statement accompanying the guidance noted, “research shows that kids using e-cigarettes are more likely to take up combustible cigarettes.”⁸¹⁷

III. THE MARCH 2019 DRAFT GUIDANCE DID NOT COVER MINT AND MENTHOL FLAVORED E-CIGARETTES, ALLOWING COMPANIES TO CONTINUE MARKETING THESE PRODUCTS

The March 2019 Draft Guidance explained that FDA would prioritize enforcement of premarket review requirements for flavored e-cigarette products—other than tobacco-, mint-, and menthol-flavored products—“that are offered for sale in ways that pose a greater risk for minors to access such products.”⁸¹⁸ Whereas manufacturers of most flavored tobacco products needed to submit PMTAs by August 2021, manufacturers of mint- and menthol-flavored tobacco products were not required to file PMTAs until August 2022.⁸¹⁹ To support this decision, FDA cited several studies evaluating the role of menthol in tobacco usage and reasoned that “[w]hile minors use mint and menthol [e-cigarette] products, it appears that they prefer them substantially less than adults prefer such flavors.”⁸²⁰ The guidance further explained, “[i]t is possible that mint- and menthol-flavored [e-cigarette] products may be important to some adults who seek to use specific [e-cigarette] products to cease combustible tobacco product use.”⁸²¹ However, the March 2019 Draft Guidance also proposed to enforce the premarket review requirements against any “[e-cigarette] products that are targeted to minors or likely to promote use of [e-cigarettes] by minors,” regardless of flavor.⁸²²

FDA’s justification for omitting menthol-flavored products from the March 2019 Draft Guidance stands in sharp contrast to statements from a 2012 report from the U.S.

⁸¹³ CTR. FOR TOBACCO PRODS., U.S. FOOD & DRUG ADMIN., MODIFICATIONS TO COMPLIANCE POLICY FOR CERTAIN DEEMED TOBACCO PRODUCTS DRAFT GUIDANCE 4 (2019) [hereinafter MARCH 2019 DRAFT GUIDANCE].

⁸¹⁴ *Id.*

⁸¹⁵ *Id.*

⁸¹⁶ *Id.*

⁸¹⁷ Statement, U.S. Food & Drug Admin., Statement from FDA Commissioner Scott Gottlieb, M.D., on Advancing New Policies Aimed at Preventing Youth Access to, and Appeal of, Flavored Tobacco Products, Including E-Cigarettes and Cigars (Mar. 13, 2019), <https://www.fda.gov/news-events/press-announcements/statement-fda-commissioner-scott-gottlieb-md-advancing-new-policies-aimed-preventing-youth-access>.

⁸¹⁸ MARCH 2019 DRAFT GUIDANCE, *supra* note 813, at 12.

⁸¹⁹ *Id.* at 4.

⁸²⁰ *Id.* at 10.

⁸²¹ *Id.* at 19.

⁸²² *Id.* at 13.

Surgeon General regarding menthol cigarettes:

Beyond being the predominant cigarette product smoked by African Americans, menthol cigarettes are popular among adolescents. In analyses of nationally representative survey data from 2004 to 2010, youth and young adults were heavy consumers of mentholated cigarettes, with menthol use particularly associated with being younger, female, and of non-White race/ethnicity. Further, the survey data indicated that use of mentholated cigarettes has either remained constant or increased from 2004–2010 in youth and young adults while rates of use of nonmenthol cigarettes has been declining.⁸²³

Moreover, FDA’s Tobacco Products Scientific Advisory Committee—which the TCA created and charged with creating a report on menthol cigarettes—found evidence indicating that menthol cigarettes promoted experimentation and regular smoking and increased the likelihood of addiction in youth smokers.⁸²⁴ It noted that “[m]ore than 80 percent of adolescent African American smokers and more than half of adolescent Hispanic smokers use menthol cigarettes. Menthol cigarettes are used by more than half of Asian American middle-school smokers.”⁸²⁵ Generally, the advisory committee found that “[u]se of menthol cigarettes is rising among adolescents, driven by a significant increase in the number of white youth ages 12–17 who are smoking menthol cigarettes.”⁸²⁶ With regard to cessation, the committee concluded that among African Americans, smokers of menthol cigarettes were less likely to quit successfully.⁸²⁷

The popularity of these flavors became more evident after JUUL stopped selling its non-traditional flavored products. As noted above, after JUUL stopped selling pods in flavors other than Tobacco, Mint, and Menthol in mid-2019, Mint sales skyrocketed “so much so that they [dwarfed] revenue for the other flavored pods combined.”⁸²⁸ At a February 2020 hearing before the Subcommittee on Oversight and Investigations of the House Committee on Energy and Commerce, current JUUL CEO K.C. Crosthwaite testified that Mint pods accounted for 70 percent of company revenue as of late 2019.⁸²⁹ According to one analyst, Mint sales earned JUUL \$2.36 billion in annualized sales—a 200 percent gain from when Mint was one of many flavors.⁸³⁰ JUUL subsequently ended sales of Mint pods due to their popularity among youth.⁸³¹ Since then, sales of menthol e-cigarettes have grown. The Truth Initiative estimated that “after JUUL

⁸²³ 2014 SURGEON GEN. REP., *supra* note 42.

⁸²⁴ U.S. FOOD & DRUG ADMIN., REPORT BY TOBACCO PRODUCTS SCIENTIFIC ADVISORY COMMITTEE (TPSAC) (Mar. 2011).

⁸²⁵ *Id.*

⁸²⁶ *Id.*

⁸²⁷ Andrea Villanti et al., *Menthol Cigarettes and the Public Health Standard: A Systematic Review*, 17 BMC PUB. HEALTH 983 (2017).

⁸²⁸ Richard Morgan, *Juul’s Mint-Flavored E-Cig Sales Skyrocketed After Other Flavors Pulled*, N.Y. POST (Sept. 11, 2019), <https://nypost.com/2019/09/11/juuls-mint-flavored-e-cig-sales-soared-after-other-flavors-pulled/>.

⁸²⁹ Vaping in America, *supra* note 373.

⁸³⁰ Morgan, *supra* note 828.

⁸³¹ Vaping in America, *supra* note 373.

voluntarily removed mint-flavored e-cigarettes, the market share of menthol-flavored products increased by almost 60% and sales increased by \$30.4 [million] during the four-week period following the removal.”⁸³²

IV. ALTHOUGH THE FEDERAL GOVERNMENT SIGNALLED IT WOULD BAN FLAVORED E-CIGARETTES, IT REVERSED COURSE

Following the rapid expansion of JUUL, and seemingly recognizing the role that flavors played in youth use of e-cigarettes, HHS signaled its intent to address the issue as part of its “ongoing work to tackle the epidemic of youth e-cigarette use.” On September 11, 2019, federal officials announced a new initiative in which FDA would issue a compliance policy “that would prioritize the agency’s enforcement of the premarket authorization requirements for non-tobacco-flavored e-cigarettes, including mint and menthol, clearing the market of unauthorized, non-tobacco-flavored e-cigarette products.”⁸³³ The prohibition would have applied to pod-based systems, such as those from JUUL, as well as open-tank systems usually found in vape shops.⁸³⁴ The press release announcing the anticipated policy noted that initial data from the 2019 NYTS “show[ed] a continued rise in the disturbing rates of youth e-cigarette use, especially through the use of non-tobacco flavors that appeal to kids.”⁸³⁵ Then-acting FDA Commissioner Ned Sharpless promised that if FDA were to “see a migration to tobacco-flavored products by kids, [FDA would] take additional steps to address youth use of these products.”⁸³⁶ Acting Commissioner Sharpless’ statement came exactly one year after Commissioner Gottlieb’s affirmation that “certain flavors are one of the principal drivers of the youth appeal of these products.”⁸³⁷

On November 17, 2019, however, The Washington Post reported that President Trump had reversed course on this comprehensive flavor ban, citing potential “job losses” as a reason for not moving forward with the proposal.⁸³⁸

⁸³² TRUTH INITIATIVE, *Weak Restrictions on Flavored E-Cigarettes Lead to Explosive Menthol Sales* (Sept. 30, 2020), <https://truthinitiative.org/research-resources/emerging-tobacco-products/weak-restrictions-flavored-e-cigarettes-lead-explosive>.

⁸³³ Press Release, U.S. Dep’t Health & Hum. Servs., Trump Administration Combating Epidemic of Youth E-Cigarette Use with Plan to Clear Market of Unauthorized, Non-Tobacco-Flavored E-Cigarette Products (Sept. 11, 2019), <https://www.fda.gov/news-events/press-announcements/trump-administration-combating-epidemic-youth-e-cigarette-use-plan-clear-market-unauthorized-non> [hereinafter 2019 HHS Release].

⁸³⁴ Premarket Tobacco Product Applications and Recordkeeping Requirements, 84 Fed. Reg. 50,566 (Sept. 25, 2019) (to be codified at 21 C.F.R. pt. 1100, 1107, 1114).

⁸³⁵ 2019 HHS Release, *supra* note 833.

⁸³⁶ *Id.*

⁸³⁷ Press Release, U.S. Food & Drug Admin., FDA Takes New Steps to Address Epidemic of Youth E-Cigarette Use, Including a Historic Action Against More Than 1,300 Retailers and 5 Major Manufacturers for Their Roles Perpetuating Youth Access (Sept. 11, 2018), <https://www.fda.gov/news-events/press-announcements/fda-takes-new-steps-address-epidemic-youth-e-cigarette-use-including-historic-action-against-more>.

⁸³⁸ Josh Dawsey & Laurie McGinley, *Trump Backs Off Flavored Vape Ban He Once Touted*, WASH. POST (Nov. 17, 2019), https://www.washingtonpost.com/national/health-science/trump-pulls-back-from-flavored-vaping-ban/2019/11/17/30853ece-07ae-11ea-924a-28d87132c7ec_story.html.

V. FDA'S MOST RECENT GUIDANCE ANNOUNCED ENFORCEMENT PRIORITIES FOR SOME, BUT NOT ALL, FLAVORED E-CIGARETTE PRODUCTS

Mr. Zeller explained to the Subcommittee that after HHS's September 2019 announcement regarding flavored products, a new study from a researcher at the University of Southern California showed that youth e-cigarette users overwhelmingly preferred mint to menthol.⁸³⁹ The study, which surveyed eighth, tenth, and twelfth grade students, found that mint fell at or near the top of the most frequently used flavors among students who had used JUUL in the past 30 days.⁸⁴⁰ In contrast, menthol was among the least frequently used flavors across all grades, along with traditional tobacco flavors.⁸⁴¹ According to Mr. Zeller, this study was an important piece of new data that required FDA to rethink its March 2019 Draft Guidance.⁸⁴²

FDA issued updated guidance on January 2, 2020 ("January 2020 Guidance").⁸⁴³ This policy outlined FDA's prioritization for reviews of PMTAs and enforcement against three categories of products:

- (1) Flavored, cartridge-based e-cigarettes other than tobacco- or menthol-flavored products);
- (2) All other e-cigarette products for which the manufacturer has failed to take (or is failing to take) adequate measures to prevent minors' access; and
- (3) Any e-cigarette product that is targeted to minors or likely to promote use by minors.⁸⁴⁴

Under the January 2020 Guidance, FDA's prioritized enforcement was scheduled to begin on February 6, 2020.⁸⁴⁵

⁸³⁹ Zeller Interview (July 2, 2020). Unlike the NYTS, this study asked questions about mint and menthol flavors separately rather than grouping the flavors together in one category. *Id.*

⁸⁴⁰ Adam Leventhal et al., *Flavors of E-Cigarettes Used by Youths in the United States*, 322 JAMA 2132 (Nov. 5, 2019).

⁸⁴¹ *Id.*

⁸⁴² Zeller Interview (July 2, 2020).

⁸⁴³ The January 2020 Guidance was revised in April 2020. U.S. FOOD & DRUG ADMIN., ENFORCEMENT PRIORITIES FOR ELECTRONIC NICOTINE DELIVERY SYSTEMS (ENDS) AND OTHER DEEMED PRODUCTS ON THE MARKET WITHOUT PREMARKET AUTHORIZATION 6 (2020) [hereinafter 2020 ENFORCEMENT PRIORITIES].

⁸⁴⁴ *Id.* at 3. FDA also announced its intent to prioritize enforcement of e-cigarette products offered for sale after September 9, 2020, and for which the manufacturer has not submitted a premarket application. FDA stated that it would continue to closely monitor and take legal action regarding sales of tobacco products to minors and other violations. *Id.*

⁸⁴⁵ *Id.*; Zeller Briefing (July 25, 2019). In connection with the AAP litigation discussed above, the court issued an order requiring that deemed tobacco products—including e-cigarettes—on the market as of August 8, 2016 for which manufacturers did not file premarket authorization applications by May 12, 2020, also be subject to FDA enforcement actions. The court subsequently clarified that its order did not restrict FDA's authority to enforce the premarket review provisions against deemed products, or categories of deemed products, prior to the May 12, 2020 submission date, or during the one-year review period. Order, *Am. Acad. of Pediatrics v. Food & Drug Admin.*, 379 F. Supp. 3d 461 (D. Md. 2019) (Case No. 8:18-cv-883 PWG) (No. 132). On April 22, 2020, the district court granted a motion for an extension of the premarket authorization application deadline to September 9, 2020 in light of the novel coronavirus

The January 2020 Guidance allowed menthol-flavored products to remain on the market with minimal oversight.⁸⁴⁶ To justify its decision to allow menthol products to remain on the market but to remove mint products, FDA pointed to recent studies, including “data from the 2019 Monitoring the Future survey [that] indicate[d] that youth use of mint- and fruit-flavored JUUL products is higher than that of menthol- and tobacco-flavored JUUL products.”⁸⁴⁷

In addition to not addressing menthol-flavored products, the January 2020 Guidance failed to extend the ban on flavors to open tank systems commonly sold by vape shops.⁸⁴⁸ FDA also explained in a footnote that the January 2020 Guidance would not apply to “completely self-contained, disposable products.”⁸⁴⁹ As a result, manufacturers can continue to sell disposable e-cigarettes in dessert and fruit flavors, which studies have indicated are popular among youth.⁸⁵⁰ Reports now indicate that many youth have switched from JUUL products to disposable e-cigarette devices.⁸⁵¹

Public health advocates have criticized the January 2020 Guidance, noting that under the new policy, e-cigarette manufacturers can still submit an application for premarket authorization for flavored products if they can demonstrate the product meets certain public health standards.⁸⁵² The Campaign for Tobacco-Free Kids described the guidance as a “roadmap for e-cigarette makers to continue addicting kids with flavored products.”⁸⁵³ In its view, the guidance was “riddled with loopholes that allow thousands of flavored e-cigarette products to remain available at more than 100,000 locations across the country, including convenience stores, gas stations and vape shops.”⁸⁵⁴ Similarly, an editorial published in *The Washington Post* criticized FDA’s selective enforcement of its guidelines, arguing that loopholes would exempt whole categories of vaping products like “e-liquids for refillable e-cigarettes in any flavor” and disposable e-

pandemic. Order, *Am. Acad. of Pediatrics v. Food & Drug Admin.*, 379 F. Supp. 3d 461 (D. Md. 2019) (Case No. 8:18-cv-883 PWG) (No. 182).

⁸⁴⁶ 2020 ENFORCEMENT PRIORITIES, *supra* note 843, at 3.

⁸⁴⁷ *Id.* at 38. Findings from the 2020 NYTS, however, suggested, “prominent menthol e-cigarette use, including among nearly one half of flavored prefilled pod or cartridge users and one quarter of flavored disposable product users.” *2020 E-cigarette Use Among Middle and High School Students*, *supra* note 80.

⁸⁴⁸ 2020 ENFORCEMENT PRIORITIES, *supra* note 843, at 44.

⁸⁴⁹ *Id.*

⁸⁵⁰ M.B. Harrell et al., *Flavored E-Cigarette Use: Characterizing Youth, Young Adult, and Adult Users*, 5 PREVENTATIVE MED. REPS. 33 (Nov. 11, 2016).

⁸⁵¹ Sheila Kaplan, *Teens Find a Big Loophole in the New Flavored Vaping Ban*, N.Y. TIMES (Jan. 31, 2020), <https://www.nytimes.com/2020/01/31/health/vaping-flavors-disposable.html>. The 2020 NYTS also noted that “during 2019–2020, disposable e-cigarette use increased approximately 1,000% (from 2.4% to 26.5%) among high school current e-cigarette users and approximately 400% (from 3.0% to 15.2%) among middle school current e-cigarette users.” *2020 E-cigarette Use Among Middle and High School Students*, *supra* note 80.

⁸⁵² Press Release, Matthew Myers, President, Campaign for Tobacco-Free Kids, *Trump Administration Policy Provides Roadmap for E-Cigarette Makers to Keep Addicting Kids with Flavored Products* (Feb. 5, 2020), https://www.tobaccofreekids.org/press-releases/2020_02_05_trump-roadmap.

⁸⁵³ *Id.*

⁸⁵⁴ *Id.*

cigarettes.⁸⁵⁵

⁸⁵⁵ Editorial Board, Opinion, *The Vaping Ban is Here, and it's Already Out of Date*, WASH. POST (Feb. 8, 2020), https://www.washingtonpost.com/opinions/the-vaping-ban-is-here-and-its-already-out-of-date/2020/02/07/c73e7c3a-492c-11ea-b4d9-29cc419287eb_story.html.

PART V: PUFF BAR SWIFTLY BECAME THE MOST POPULAR E-CIGARETTE BRAND AMONG YOUTH AFTER JUUL WAS LARGELY SIDELINED

After FDA prioritized enforcement of certain flavored e-cigarette products, JUUL non-traditional flavors were taken off the market and marketing techniques halted. Other e-cigarette producers were able to fill the void left by JUUL's removal of flavors. Puff Bar soon became the most popular e-cigarette brand among youth. Sales of Puff Bar e-cigarette products increased dramatically in the United States after the company launched in 2019. At the same time, Puff Bar's popularity among youth soared such that the 2021 and 2022 NYTSs reported that Puff Bar was the most popular e-cigarette brand among youth.

Puff Bar was introduced to the market by Cool Clouds Distribution, Inc. ("Cool Clouds"), but was soon acquired by two individuals, Nick Minas and Patrick Beltran, who became co-CEOs of the company and continued the popular brand. The Subcommittee learned that Puff Bar's co-CEOs were aware of the rise of youth vaping and the popularity of Puff Bar products among youth when they acquired the company. Puff Bar's co-CEOs admitted to learning from JUUL's success and mistakes and intentionally adopting some of JUUL's practices when they took over Puff Bar. Despite knowing that its products appealed to youth, Puff Bar took limited efforts to curb youth access and youth appeal of its products.

I. PUFF BAR'S RAPID RISE IN YOUTH POPULARITY FILLED A VOID IN THE MARKET LEFT BY JUUL'S REMOVAL OF FLAVORS

In 2019, as JUUL suspended selling flavored e-cigarettes, Puff Bar came on the market in the United States. Puff Bar's flavored e-cigarette products popularized disposable e-cigarettes and Puff Bar soon became the most popular brand among youth. Puff Bar entered the U.S. market offering flavored disposable e-cigarettes in a variety of flavors. By spring of 2020, Puff Bar sales reached over \$3 million a week.⁸⁵⁶ At the same time, Puff Bar's popularity among youth surged. One study found that Puff Bar was the most popular disposable brand by March 2020, and the 2020 NYTS showed Puff Bar was gaining in popularity among youth.⁸⁵⁷ According to Puff Bar's current co-CEOs, Cool Clouds voluntarily halted Puff Bar sales in July 2020 after facing

⁸⁵⁶ Sheila Kaplan, *Lawmakers Say Puff Bar Used Pandemic to Market to Teens*, N.Y. TIMES (June 2, 2022), <https://www.nytimes.com/2020/06/02/health/puff-bar-teens.html>.

⁸⁵⁷ TRUTH INITIATIVE, *Dangerous Loopholes, Young E-Cigarette Users Report Swapping Products as Vaping Policies Change* (May 2020), <https://truthinitiative.org/research-resources/emerging-tobacco-products/dangerous-loopholes-young-e-cigarette-users-report>; Wang et al., *supra* note 98.

public scrutiny for its youth appeal.⁸⁵⁸ One week after suspending sales, FDA issued a warning letter to Puff Bar to remove its products from the market.⁸⁵⁹

In February 2021, Puff Bar relaunched with co-CEOs Nick Minas and Patrick Beltran leading the company. Puff Bar brought back its disposable e-cigarettes in a portfolio of flavors that were again mainly fruit-based. However, to avoid FDA oversight, Puff Bar introduced products containing synthetic nicotine, which was outside FDA's jurisdiction at the time of the relaunch.⁸⁶⁰ Even after its relaunch, Puff Bar continued to be popular among youth. The 2021 and 2022 NYTSs found that Puff Bar was the most popular e-cigarette brand among youth.⁸⁶¹

A. Puff Bar Products and Popularity in 2019-2020

Puff Bar entered the U.S. market in 2019 and was owned by Cool Clouds.⁸⁶² Cool Clouds distributed a number of Puff Bar disposable e-cigarettes, including Puff

⁸⁵⁸ Interview with Nick Minas, Co-CEO, Puff Bar (Sept. 27, 2023) [hereinafter Minas Interview (Sept. 27, 2023)]; Interview with Patrick Beltran, Co-CEO, Puff Bar (Sept. 28, 2023) [hereinafter Beltran Interview (Sept. 28, 2023)]; *Puff Bar Suspends Sales in the United States*, TOBACCO REPORTER (July 14, 2020), <https://tobaccoreporter.com/2020/07/14/puff-bar-suspends-u-s-sales/>. See also Jennifer Maloney, *The 27-Year-Old Friends Behind Puff Bar - Teens' Favorite E-Cigarette*, WALL ST. J. (Oct. 11, 2021), <https://www.wsj.com/articles/the-27-year-old-friends-behind-puff-barteens-favorite-e-cigarette-11633978700>.

⁸⁵⁹ Letter from Ann Simoneau, Dir., Off. of Compliance & Enf't, Ctr. for Tobacco Prods., U.S. Food & Drug Admin., to Umais Abubaker, Puff Bar (July 20, 2020), <https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/cool-clouds-distribution-inc-dba-puff-bar-608526-07202020>; Press Release, U.S. Food & Drug Admin., FDA Notifies Companies, Including Puff Bar, to Remove Flavored Disposable E-Cigarettes and Youth-Appealing E-Liquids from Market for Not Having Required Authorization (July 20, 2020), <https://www.fda.gov/news-events/press-announcements/fda-notifies-companies-including-puff-bar-remove-flavored-disposable-e-cigarettes-and-youth>.

⁸⁶⁰ Minas Interview (Sept. 27, 2023); Beltran Interview (Sept. 28, 2023); Press Release, Ctr. for Tobacco Prods., U.S. Food & Drug Admin., New Law Clarifies FDA Authority to Regulate Synthetic Nicotine (Mar. 18, 2022), <https://www.fda.gov/tobacco-products/ctp-newsroom/new-law-clarifies-fda-authority-regulate-synthetic-nicotine>.

⁸⁶¹ *2021 E-cigarette Use Among Middle and High School Students*, *supra* note 82; *2022 E-cigarette Use Among Middle and High School Students*, *supra* note 84.

⁸⁶² Maloney, *The 27-Year-Old Friends Behind Puff Bar*, *supra* note 858; Minas Interview (Sept. 27, 2023); Beltran Interview (Sept. 28, 2023).

Bar,⁸⁶³ Puff Glow,⁸⁶⁴ Puff Flow,⁸⁶⁵ Puff PLUS,⁸⁶⁶ Puff KRUSH,⁸⁶⁷ Puff Mini,⁸⁶⁸ and Puff XXL.⁸⁶⁹ These products came in non-traditional fruit flavors, such as Banana Ice, Blue Razz, O.M.G. (Orange, Mango, Guava), Mango, Pink Lemonade, and Lychee Ice.⁸⁷⁰

By January 2020, Puff Bar sales reached \$3.3 million, up from \$14,000 a few months prior.⁸⁷¹ Puff Bar continued this success throughout 2020. Based on data tracking sales at convenience stores, Puff Bar sales consistently topped over \$3 million a week from April to June 2020.⁸⁷²

⁸⁶³ See *Collection: Puff Bar*, Rsch. into the Impact of Tobacco Advert., STAN. UNIV., <https://tobacco.stanford.edu/disposables/puff-bar-main/puff-bar/>. Product flavors included: Pomegranate, Sour Apple, Blueberry Ice, Blueberry, Pink Lemonade, Grape, Banana Ice, Pineapple Lemonade, O.M.G., Lush ice, Watermelon, Lychee Ice, Blue Razz, Strawberry, Mango, and Cool Mint.

⁸⁶⁴ See *Collection: Puff Glow*, Rsch. into the Impact of Tobacco Advert., STAN. UNIV., <https://tobacco.stanford.edu/disposables/puff-bar-main/puff-glow/>. Product flavors included: Apple Peach, Frozen Banana, Peach Ice, Mango Apple Pear, Strawberry Donut, and Mint Chip.

⁸⁶⁵ See *Collection: Puff Flow*, Rsch. into the Impact of Tobacco Advert., STAN. UNIV., <https://tobacco.stanford.edu/disposables/puff-bar-main/puff-flow/>. Product flavors included: Kiwi Strawberry, Aloe Mango Melon Ice, Grape Apple Pear, Strawberry Banana, Papaya Banana, Peach Ice, Guava Ice, and Lychee Ice.

⁸⁶⁶ See *Collection: Puff Plus*, Rsch. into the Impact of Tobacco Advert., STAN. UNIV., <https://tobacco.stanford.edu/disposables/puff-bar-main/puff-plus/>. Product flavors included: Guava Ice, Watermelon, Strawberry Watermelon, Cool Mint, Lychee Ice, Peach Ice, and Mixed Berries.

⁸⁶⁷ See *Collection: Puff Krush*, Rsch. into the Impact of Tobacco Advert., STAN. UNIV., <https://tobacco.stanford.edu/disposables/puff-bar-main/puff-krush/>. Product flavors included: Cotton Candy, Mango, Sour Apple, Kiwi Strawberry, Lychee Ice, Cool Mint Ice, Watermelon Ice, and Peach Ice.

⁸⁶⁸ See *Collection: Puff Mini*, Rsch. into the Impact of Tobacco Advert., STAN. UNIV., <https://tobacco.stanford.edu/disposables/puff-bar-main/puff-mini/>. Product flavors included: Strawberry Smoothie, Cool Mint, Lemonade, Pomelo Ice, Mango Slush, Mixed Fruit, Energy Drink, Passionfruit, Frozen Cantaloupe, and Cinnamon Tobacco.

⁸⁶⁹ See *Collection: Puff XXL*, Rsch. into the Impact of Tobacco Advert., STAN. UNIV., <https://tobacco.stanford.edu/disposables/puff-bar-main/puff-xxl/>. Product flavors included: Pineapple Grape, Watermelon Cherry, Mango Orange Pomelo, Cranberry Lemon Ice, Mixed Berries Ice, Papaya Strawberry, Lush Ice, Cool Mint, Banana Ice, and Aloe Mango Melon.

⁸⁷⁰ See *id.*

⁸⁷¹ Sophie Alexander & Angelica Peebles, *Upstart Vaping Company Plans Pullback After Outcry Over Loophole*, BLOOMBERG (Feb. 20, 2020), <https://www.bloomberg.com/news/features/2020-02-20/puff-bars-disposable-vapes-exploit-us-flavor-ban-loophole>.

⁸⁷² Kaplan, *supra* note 856.



Figure 20: The Puff Bar in Banana Ice, Lychee Ice, O.M.G., and Pink Lemonade Flavors⁸⁷³

As Puff Bar sales skyrocketed, the company's popularity among youth also surged. The 2020 NYTS, which collected data between January and March 2020, found that Puff Bar was the fourth most popular brand among high school e-cigarette users—7.3 percent of high school e-cigarette users wrote in Puff Bar as their usual brand although it was not named in the survey.⁸⁷⁴ As discussed above, the survey also showed the dramatic rise in popularity of disposable e-cigarettes among middle and high school students. Disposable e-cigarette use had increased nearly 1,000 percent among high school students and approximately 400 percent among middle school students.⁸⁷⁵ Furthermore, a Truth Initiative study found that by March 2020, disposable e-cigarettes were the most popular device type used by youth, and Puff Bar was the most popular disposable brand.⁸⁷⁶

Puff Bar's popularity among youth faced public scrutiny.⁸⁷⁷ In June 2020, the House Committee on Oversight and Reform Subcommittee on Economic and Consumer Policy requested that FDA take action against Puff Bar for marketing directly to youth.⁸⁷⁸ In mid-July 2020, Puff Bar voluntarily halted its online sales and distribution

⁸⁷³ #34, *Collection: Puff Bar*, Rsch. into the Impact of Tobacco Advert., STAN. UNIV., <https://tobacco.stanford.edu/disposables/puff-bar-main/puff-bar/#collection-34>; #47, *Collection: Puff Bar*, Rsch. into the Impact of Tobacco Advert., STAN. UNIV., <https://tobacco.stanford.edu/disposables/puff-bar-main/puff-bar/#collection-47>; #52, *Collection: Puff Bar*, Rsch. into the Impact of Tobacco Advert., STAN. UNIV., <https://tobacco.stanford.edu/disposables/puff-bar-main/puff-bar/#collection-52>; #48, *Collection: Puff Bar*, Rsch. into the Impact of Tobacco Advert., STAN. UNIV., <https://tobacco.stanford.edu/disposables/puff-bar-main/puff-bar/#collection-48>.

⁸⁷⁴ Wang et al., *supra* note 98.

⁸⁷⁵ 2020 *E-cigarette Use Among Middle and High School Students*, *supra* note 80.

⁸⁷⁶ TRUTH INITIATIVE, *Dangerous Loopholes*, *supra* note 857.

⁸⁷⁷ See e.g., Alexander & Peebles, *supra* note 871.

⁸⁷⁸ Letter from Raja Krishnamoorthi, Chairman H. Comm. on Oversight & Reform Subcomm. on Econ. & Consumer Pol'y, to Stephen M. Hahn, Comm'r U.S. Food & Drug Admin. (June 1, 2020), <https://oversightdemocrats.house.gov/sites/democrats.oversight.house.gov/files/2020-06-01%20RK%20to%20Hahn-%20FDA%20Puff%20Bar%20Products.pdf>.

in the United States.⁸⁷⁹ One week after suspending its sales, FDA issued a warning letter to Puff Bar to remove its “youth-appealing” products from the market.⁸⁸⁰

B. Puff Bar Products and Popularity in 2021-2022

After suspending sales in July 2020, Puff Bar relaunched in February 2021 under co-CEOs Mr. Minas and Mr. Beltran. Puff Bar relaunched its disposable e-cigarette products in a variety of flavors.⁸⁸¹ These products included the Puff Bar,⁸⁸² Puff Plus,⁸⁸³ Puff Flow,⁸⁸⁴ and Puff Max and came in the same flavors previously offered by Puff Bar, such as Banana Ice, Lychee Ice, and Cool Mint.⁸⁸⁵ To avoid regulatory oversight, Puff Bar’s e-cigarettes contained synthetic nicotine—which was outside FDA jurisdiction at the time—in a five percent concentration.⁸⁸⁶ In April 2021, Puff Bar was the most popular disposable e-cigarette, with 51.3 percent of the disposable market share, followed by BIDI stick with 24 percent.⁸⁸⁷ One study that analyzed Puff Bar point-of-sales data from February to May 2021 found that the company’s monthly sales levels ranged from \$4.63–\$7.11 million and a median of \$5.98 million.⁸⁸⁸

⁸⁷⁹ TOBACCO REPORTER, *Puff Bar Suspends Sales*, *supra* note 858.

⁸⁸⁰ Letter from Ann Simoneau, Dir., Off. of Compliance & Enf’t, Ctr. for Tobacco Prods., U.S. Food & Drug Admin., to Umair Abubaker, Puff Bar (July 20, 2020), <https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/cool-clouds-distribution-inc-dba-puff-bar-608526-07202020>; Press Release, U.S. Food & Drug Admin., FDA Notifies Companies, Including Puff Bar, to Remove Flavored Disposable E-Cigarettes and Youth-Appealing E-Liquids from Market for Not Having Required Authorization (July 20, 2020), <https://www.fda.gov/news-events/press-announcements/fda-notifies-companies-including-puff-bar-remove-flavored-disposable-e-cigarettes-and-youth>.

⁸⁸¹ “PVG2, LLC – 1.30.2023 Response to FTC Order.pdf”; “SUBSenateResponses2(nick@puffbar.com).pdf”.

⁸⁸² “PVG2, LLC – 1.30.2023 Response to FTC Order.pdf”. Product flavors included: Banana Ice, Blue Razz, Blueberry Ice, Cool Mint, Grape, Lemon Ice, Lush, Lychee Ice, Mango, Melon Ice, Peach Ice, Strawberry, Strawberry Banana, Tobacco, and Watermelon.

⁸⁸³ *Id.* Product flavors included: Banana Ice, Blue Razz, Blueberry Ice, Cool Mint, Guava Ice, Lemon Ice, Lush, Lychee Ice, Mango, Menthol, Mixed Berries, Peach Ice, Straw Watermelon, and Strawberry Banana.

⁸⁸⁴ *Id.* Product flavors included: Aloe Grape, Banana Ice, Blue Razz, Blueberry Ice, Cool Mint, Cran Lemon, Guava Ice, Lemon Ice, Lychee Ice, Mango, Menthol, Passion Fruit, and Peace Ice.

⁸⁸⁵ Minas Interview (Sept. 27, 2023). Puff Max was a completely new product introduced by the new iteration of Puff Bar. This product was distinguished by its higher puff count. *Id.*

⁸⁸⁶ Minas Interview (Sept. 27, 2023); Beltran Interview (Sept. 28, 2023); Press Release, Ctr. for Tobacco Prods., U.S. Food & Drug Admin., New Law Clarifies FDA Authority to Regulate Synthetic Nicotine (Mar. 18, 2022), <https://www.fda.gov/tobacco-products/ctp-newsroom/new-law-clarifies-fda-authority-regulate-synthetic-nicotine>.

⁸⁸⁷ TRUTH INITIATIVE, *E-Cigarettes*, *supra* note 58.

⁸⁸⁸ Anuja Majmundar et al., *Trends in public interest in shopping and point-of-sales of JUUL and Puff Bar 2019-2021*, 32 TOBACCO CONTROL e236-37 (2022).



Figure 21: 2021-2022 Puff Bar, Puff Plus, and Puff Max Products and Flavors⁸⁸⁹

Even after its relaunch, Puff Bar continued to be popular among youth. As discussed above, the 2021 and 2022 NYTSs found that Puff Bar was the most popular e-cigarette brand among youth during these years. Specifically, the 2021 NYTS found that among high school current e-cigarette users, 26.1 percent reported that their usual brand was Puff Bar, and among middle school current users, 30.3 percent reported that their usual brand was Puff Bar.⁸⁹⁰ The 2022 NYTS showed that among current e-cigarette users, Puff Bar was the most commonly reported brand used in the past 30 days by both middle and high school students (29.7 percent), and among current middle and high school e-cigarette users, 14.5 percent reported that the brand they usually used was Puff Bar.⁸⁹¹

⁸⁸⁹ PUFF00014359; PUFF00014360; PUFF00014362.

⁸⁹⁰ Among high school current e-cigarette users, Puff Bar was followed by Vuse (10.8 percent), SMOK (9.6 percent), JUUL (5.7 percent), and Suorin (2.3 percent). Among middle school current users, besides Puff Bar, 12.5 percent reported JUUL. In addition, 15.6 percent of high school users and 19.3 percent of middle school users reported not knowing the e-cigarette brand they usually used. *2021 E-cigarette Use Among Middle and High School Students, supra* note 82, at 1387.

⁸⁹¹ The other brands used in the past 30 days by middle and high school students included Vuse (23.6 percent), JUUL (22 percent), SMOK (13.5 percent), NJOY (8.3 percent), Hyde (7.3 percent), and blu

II. PUFF BAR'S EARLY ORIGINS ARE MURKY, BUT TWO INEXPERIENCED CEOS WERE ABLE TO ACQUIRE THE BRAND AND CONTINUE ITS SUCCESS

In 2019, Cool Clouds introduced Puff Bar to the U.S. Market.⁸⁹² However, the brand has been associated with various Chinese and American companies, including DS Technology Licensing LLC (“DS Technology”), which sold Puff Bar to Mr. Minas and Mr. Beltran in 2021. Before Mr. Minas and Mr. Beltran acquired Puff Bar, they contributed to the company’s success in 2020. They operated PuffBar.com and ran email campaigns on behalf of then-owner Cool Clouds from February 2020 to July 2020—until the company temporarily stopped sales due to youth use.⁸⁹³ In 2021, Mr. Minas and Mr. Beltran acquired the brand for themselves and sought to continue Puff Bar despite public scrutiny.⁸⁹⁴

A. The Early Origins of Puff Bar and Cool Clouds

The Puff Bar brand has been associated with various American and Chinese companies. According to Dr. Jackler and the SRITA team, a Chinese company called Shenzhen Daosen Steam Technology Co., Ltd., made the first trademark application for a Puff Bar product on July 1, 2019.⁸⁹⁵ One month later, Cool Clouds applied for Puff Bar’s first trademark in the United States.⁸⁹⁶

Cool Clouds owned Puff Bar when it entered the U.S. market in 2019.⁸⁹⁷ Cool Clouds functioned as its operating company, distributing and selling Puff Bar products in the United States.⁸⁹⁸ Documents filed with the California Secretary of State listed Umair Abubaker, who also goes by Max Baker, as Cool Clouds’ CEO, Secretary, and Chief Financial Officer.⁸⁹⁹ Puff Bar’s ownership also included two other individuals—Abdurrahman Yousuf and Saquib (Zack) Shoaib.⁹⁰⁰

(6.5 percent). Among current e-cigarette users, the other reported brands used were Vuse (12.5 percent), Hyde (5.5 percent), and SMOK (4 percent). Approximately one fifth (21.8 percent) of current e-cigarette users reported “some other brand” as their usual brand. *2022 E-cigarette Use Among Middle and High School Students*, *supra* note 84, at 1283.

⁸⁹² Maloney, *The 27-Year-Old Friends Behind Puff Bar*, *supra* note 858; Minas Interview (Sept. 27, 2023); Beltran Interview (Sept. 28, 2023).

⁸⁹³ Minas Interview (Sept. 27, 2023); Beltran Interview (Sept. 28, 2023).

⁸⁹⁴ Minas Interview (Sept. 27, 2023); Beltran Interview (Sept. 28, 2023).

⁸⁹⁵ Eli Wolfe, *Lifting the veil on a controversial e-cigarette company - sort of*, INVESTIGATIVE REPORTING WORKSHOP (July 10, 2020), <https://archive.investigativereportingworkshop.org/news/lifting-the-veil-on-a-controversial-e-cigarette-company-sort-of/>.

⁸⁹⁶ *Id.*

⁸⁹⁷ Maloney, *The 27-Year-Old Friends Behind Puff Bar*, *supra* note 858; Minas Interview (Sept. 27, 2023); Beltran Interview (Sept. 28, 2023).

⁸⁹⁸ Maloney, *The 27-Year-Old Friends Behind Puff Bar*, *supra* note 858; Minas Interview (Sept. 27, 2023); Beltran Interview (Sept. 28, 2023).

⁸⁹⁹ State of California, Secretary of State, Statement of Information, Cool Clouds Distribution, Inc., July 30, 2019.

⁹⁰⁰ Minas Interview (Sept. 27, 2023); Beltran Interview (Sept. 28, 2023); Briefing with Puff Bar (June 2, 2023).

Over the next year, DS Vaping, a Chinese company, filed multiple trademarks for Puff Bar products in China.⁹⁰¹ In early 2020, DS Technology, a Delaware corporation that may have had ties to DS Vaping, the Chinese manufacturer of Puff Bar products, started registering trademarks for Puff Bar products.⁹⁰² Due to the scrutiny Puff Bar began receiving in 2020, Cool Clouds transferred Puff Bar’s trademarks to DS Technology.⁹⁰³ Mr. Minas told the Subcommittee that he believed DS Technology was a holding company controlled by Cool Clouds CEO Mr. Abubaker and other individuals.⁹⁰⁴ Mr. Beltran thought the owners of Cool Clouds wanted to protect Puff Bar trademarks from “lawsuits and potential liability” and therefore transferred them to this entity.⁹⁰⁵ DS Technology is also the entity that sold Puff Bar to Mr. Minas and Mr. Beltran.⁹⁰⁶

B. Mr. Minas and Mr. Beltran Contributed to Puff Bar’s Success Before Becoming Co-CEOs of the Company

Today, Puff Bar is owned by Mr. Minas and Mr. Beltran. Before acquiring Puff Bar in 2021, they were involved with contributing to the company’s success. In 2020, the owners of Cool Clouds approached Mr. Minas and Mr. Beltran to run the online retail website for Puff Bar, PuffBar.com.⁹⁰⁷ This relationship led to the two individuals later becoming co-CEOs of the company.

Mr. Minas and Mr. Beltran are childhood friends from Southern California.⁹⁰⁸ Both told the Subcommittee that they consider themselves entrepreneurs.⁹⁰⁹ One of Mr. Minas’s early business ventures included purchasing e-cigarettes from a distributor and selling them on Amazon out of his mother’s garage.⁹¹⁰ After receiving customer complaints for failing to complete orders, Amazon banned Mr. Minas for life as a seller.⁹¹¹ Mr. Beltran and Mr. Minas subsequently began selling e-liquid—a nicotine solution used inside an e-cigarette—on eBay and received repeated warnings of bans for violating the platform’s rule against selling tobacco products.⁹¹²

In 2017, Mr. Minas and Mr. Beltran created Eliquidstop.com (“Eliquidstop”) to sell products directly to consumers due to restrictions on e-commerce websites like Amazon

⁹⁰¹ Wolfe, *supra* note 895.

⁹⁰² *Id.*

⁹⁰³ Maloney, *The 27-Year-Old Friends Behind Puff Bar*, *supra* note 858; Beltran Interview (Sept. 28, 2023).

⁹⁰⁴ Minas Interview (Sept. 27, 2023).

⁹⁰⁵ Beltran Interview (Sept. 28, 2023).

⁹⁰⁶ “DS EVO Agreement – Fully Executed (1)”.

⁹⁰⁷ Minas Interview (Sept. 27, 2023); Beltran Interview (Sept. 28, 2023).

⁹⁰⁸ *Puff Bar CEOs on the company behind the popular e-cigarette brand: “There was a lot of shadowiness before”*, CBS NEWS (Nov. 19, 2021), <https://www.cbsnews.com/news/puff-bar-e-cigarette-ceos-fda/>.

⁹⁰⁹ Minas Interview (Sept. 27, 2023); Beltran Interview (Sept. 28, 2023).

⁹¹⁰ Wolfe, *supra* note 895.

⁹¹¹ *Id.*

⁹¹² *Id.*

and eBay.⁹¹³ They sold e-liquid and vape products on the site and claimed about \$2 million in sales by late 2018.⁹¹⁴ According to Mr. Beltran, the company had \$3 million in revenue in its best year.⁹¹⁵ In October 2019, New York City sued Eliiquidstop for allegedly selling e-cigarette products to minors.⁹¹⁶ The complaint alleged that Eliiquidstop's conduct was "particularly egregious" because it continued to sell e-cigarettes to underage purchasers after the company received and responded to a Better Business Bureau complaint and noted that the company used social media marketing and offered products that mimicked food products like "Cloud Nurdz" and "Unicorn Treats" that appeared to target youth.⁹¹⁷ On April 13, 2020, FDA sent a warning letter to Eliiquidstop and Mr. Minas for illegally selling multiple e-cigarette products.⁹¹⁸

Mr. Minas and Mr. Beltran's Eliiquidstop had been a loyal customer of Cool Clouds,⁹¹⁹ spending a minimum of \$100,000 every month to restock Puff Bar products sold on the Eliiquidstop website.⁹²⁰ This relationship led to Mr. Minas and Mr. Beltran's involvement with running Puff Bar's retail website.⁹²¹ Specifically, Mr. Minas and Mr. Beltran signed a "partnership agreement" with Mr. Shoaib, one of the owners of Cool Clouds, on February 3, 2020.⁹²² The partnership agreement established an entity called "Puff inc." for the purpose of managing the website PuffBar.com.⁹²³

Under the agreement, Mr. Minas and Mr. Beltran each received 20 percent of the entity's net profits and losses while Mr. Shoaib received 60 percent.⁹²⁴ On February 21, 2020, Mr. Minas and Mr. Beltran incorporated Puff Bar, a California corporation not to be confused with the Puff Bar owned by Cool Clouds.⁹²⁵ Mr. Minas was listed as CEO, and according to responses filed in the Lara v. Puff Bar lawsuit, he "oversaw and managed the back-end operation of Puff Bar, including fulfillment and logistics, ordering and importing Puff Bar products from manufacturers and distributors, and management of inventory" for PuffBar.com.⁹²⁶ As Chief Marketing Officer, Secretary, Chief Financial Officer, and Director, Mr. Beltran "focused on the development and operations of the

⁹¹³ *Id.*; Minas Interview (Sept. 27, 2023); Beltran Interview (Sept. 28, 2023).

⁹¹⁴ Wolfe, *supra* note 895.

⁹¹⁵ Beltran Interview (Sept. 28, 2023).

⁹¹⁶ Complaint, City of New York v. Artisan Vapor Franchise, LLC (E.D.N.Y. Oct. 8, 2019) (Case no. 1:19-cv-05693), <https://www.nyc.gov/assets/home/downloads/pdf/resources/2019/2019-10-08-final-complaint-as-filed-nyc-v-artisan-vapor-franchise-llc.pdf>.

⁹¹⁷ *Id.*

⁹¹⁸ Letter from Ann Simoneau, Dir., Off. of Compliance & Enf't, Ctr. for Tobacco Prods., U.S. Food & Drug Admin., to Nick Minas, Eliiquidstop LLC (Apr. 13, 2020), <https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/eliiquidstop-llc-607003-04132020>. According to Mr. Beltran, they sold Eliiquidstop to a former partner in 2020. Beltran Interview (Sept. 28, 2023).

⁹¹⁹ Minas Interview (Sept. 27, 2023).

⁹²⁰ *Id.*

⁹²¹ *Id.*; Beltran Interview (Sept. 28, 2023).

⁹²² "Puff Internal Agreement copy".

⁹²³ *Id.*

⁹²⁴ *Id.*

⁹²⁵ PUFFBAR00000002-3; PUFFBAR00000386.

⁹²⁶ PUFFBAR00000002-3; PUFFBAR00000387.

website and email marketing of Puff Bar.”⁹²⁷ Mr. Minas and Mr. Beltran operated Puff Bar’s website and email marketing from February 2020 to July 2020,⁹²⁸ when the company stopped sales due to public scrutiny for youth appeal. During this time frame, Mr. Minas said “hundreds of millions of dollars” of Puff Bar products were sold.⁹²⁹

C. Mr. Minas and Mr. Beltran Acquired and Sought to Continue Puff Bar Despite Public Scrutiny

According to Mr. Minas and Mr. Beltran, due to increased scrutiny, Cool Clouds stopped all sales of Puff Bar products in July 2020.⁹³⁰ The owners of Cool Clouds wanted to shut down Puff Bar completely, but Mr. Minas and Mr. Beltran wanted to continue the brand.⁹³¹ According to Mr. Minas, it did not “make a whole lot of sense” to stop a company with “a lot of momentum” and he did not “want such a big brand just to die.”⁹³² Mr. Beltran similarly said that he “saw a lot of value” in the Puff Bar brand and felt that he and Mr. Minas “had a lot of solutions” that the two “could try to implement” regarding the “underage usage issue.”⁹³³

Mr. Minas and Mr. Beltran described their acquisition process during interviews with the Subcommittee. They said that they personally negotiated with Mr. Abubaker regarding the sale of Puff Bar.⁹³⁴ Initially, Mr. Minas said that Mr. Abubaker offered to sell the company for \$25 million, an amount Mr. Minas thought was “ridiculous” because the company had “lost a lot of momentum from pulling off market.”⁹³⁵ Additionally, they claimed that Mr. Abubaker failed to provide supporting documents or other information justifying the price, yet they proceeded with the acquisition.⁹³⁶

After months of negotiations, Mr. Minas and Mr. Beltran, under the entities PVG2, LLC (“PVG2”) and EVO Brands, LLC (“EVO Brands”), completed the acquisition of the Puff Bar assets from DS Technology for \$17.5 million in January 2021.⁹³⁷ Mr. Beltran and Mr. Minas both told the Subcommittee that they purchased Puff Bar without conducting any due diligence or viewing company financial documents.⁹³⁸ Despite the lack of information, they believed they could generate that revenue in about two

⁹²⁷ PUFFBAR00000002-3; PUFFBAR00000387.

⁹²⁸ PUFFBAR00000387.

⁹²⁹ Minas Interview (Sept. 27, 2023).

⁹³⁰ Maloney, *The 27-Year-Old Friends Behind Puff Bar*, *supra* note 858; Minas Interview (Sept. 27, 2023); Beltran Interview (Sept. 28, 2023).

⁹³¹ Maloney, *The 27-Year-Old Friends Behind Puff Bar*, *supra* note 858; Minas Interview (Sept. 27, 2023); Beltran Interview (Sept. 28, 2023).

⁹³² Minas Interview (Sept. 27, 2023).

⁹³³ Beltran Interview (Sept. 28, 2023).

⁹³⁴ *Id.*, Minas Interview (Sept. 27, 2023).

⁹³⁵ Minas Interview (Sept. 27, 2023).

⁹³⁶ *Id.*; Beltran Interview (Sept. 28, 2023).

⁹³⁷ “DS EVO Agreement – Fully Executed (1)”; Beltran Interview (Sept. 28, 2023). According to the co-CEOs, they have paid approximately \$3 million of the \$17.5 million. Minas Interview (Sept. 27, 2023); Beltran Interview (Sept. 28, 2023).

⁹³⁸ Minas Interview (Sept. 27, 2023); Beltran Interview (Sept. 28, 2023).

years.⁹³⁹ Mr. Beltran described himself and Mr. Minas as “inexperienced” negotiators who succumbed to common negotiation pressure tactics to seal the deal.⁹⁴⁰ Mr. Minas told the Subcommittee that he “wasn’t familiar with running a large corporation” and that “in hindsight” he would not have agreed to the \$17.5 million amount.⁹⁴¹

III. PUFF BAR LEARNED FROM JUUL’S SUCCESSES AND INTENTIONALLY ADOPTED SOME OF JUUL’S PRACTICES AND AVOIDED SOME OF ITS MISTAKES

Puff Bar benefited when JUUL pulled its non-traditional flavors from the market. Mr. Minas said that Puff Bar was able to “piggyback off of JUUL” due to its similar device shape and portfolio of flavors.⁹⁴² Similar to JUUL, Puff Bar marketed and profited from a portfolio of non-traditional flavors, which the co-CEOs said were “critical” and “extremely important” to the company.⁹⁴³ Puff Bar knowingly adopted certain JUUL practices and also learned from JUUL’s mistakes. Influenced by JUUL’s “simple” branding, Puff Bar simplified flavor names and took away flavors offered by the company under Cool Clouds.⁹⁴⁴ Puff Bar followed JUUL’s lead by introducing e-cigarettes with a five percent nicotine concentration.⁹⁴⁵ Puff Bar also learned from JUUL’s mistakes, and avoided traditional marketing efforts and social media use.⁹⁴⁶ Two email campaigns during the 2020 COVID-19 pandemic received similar backlash as JUUL for appealing to youth. Similar to JUUL, Puff Bar benefited from brand notoriety and user-generated social media content.

A. Puff Bar Benefited from JUUL’s Downfall and Ultimately Developed a Similar Reputation for Its Youth Appeal

As explained in Part IV above, FDA’s 2020 updated guidance prioritized enforcement against flavored, cartridge-based e-cigarettes, like JUUL, but allowed loopholes to remain, including exempting flavored disposable e-cigarettes.⁹⁴⁷ As JUUL pulled its flavored e-cigarettes from the market in October-2019,⁹⁴⁸ Puff Bar benefited when it came on the market in 2019. Mr. Minas said that “timing was everything,” and that JUUL’s removal of non-traditional flavors “was a perfect moment in time for Puff success.”⁹⁴⁹ Mr. Minas said that Puff Bar’s success was also a “piggyback off of JUUL” due to its similar device shape to JUUL’s e-cigarette device.⁹⁵⁰ Mr. Beltran explained that the similarities in device shape allowed Puff Bar to have “natural and organic

⁹³⁹ Minas Interview (Sept. 27, 2023); Beltran Interview (Sept. 28, 2023).

⁹⁴⁰ Beltran Interview (Sept. 28, 2023).

⁹⁴¹ Minas Interview (Sept. 27, 2023).

⁹⁴² *Id.*; Beltran Interview (Sept. 28, 2023).

⁹⁴³ Minas Interview (Sept. 27, 2023); Beltran Interview (Sept. 28, 2023).

⁹⁴⁴ Minas Interview (Sept. 27, 2023); Beltran Interview (Sept. 28, 2023).

⁹⁴⁵ Minas Interview (Sept. 27, 2023); Beltran Interview (Sept. 28, 2023).

⁹⁴⁶ Minas Interview (Sept. 27, 2023); Beltran Interview (Sept. 28, 2023).

⁹⁴⁷ *See supra* Part IV, Section V.

⁹⁴⁸ JUUL Labs, Inc., *JUUL Labs Suspends Sale of Non-Tobacco, Non-Menthol-Based Products* (Oct. 17, 2019), <https://www.juulabs.com/juul-labs-suspends-sale-of-non-tobacco-non-menthol-based-flavors-in-the-u-s/>.

⁹⁴⁹ Minas Interview (Sept. 27, 2023).

⁹⁵⁰ *Id.*

growth in the market” through “strong distribution channels.”⁹⁵¹ He noted that when Cool Clouds introduced Puff Bar products in 2019, the company did not have a marketing plan, except window posters and “light marketing” at individual retail stores.⁹⁵² Despite these minimal marketing efforts, Puff Bar products became popular by 2020, in part due to its similarities to JUUL’s device and because JUUL pulled its non-traditional flavors from the market.⁹⁵³



Figure 22: Puff Bar (left) and JUUL (right) Device Comparison⁹⁵⁴

Although Puff Bar learned and gained from JUUL’s actions and characteristics, Puff Bar similarly received negative scrutiny for appealing to youth. Mr. Minas believed that Puff Bar was the next most scrutinized brand after JUUL.⁹⁵⁵ Mr. Beltran said that JUUL had been “slammed” for its flavors, and because Puff Bar had a lot of flavors, the company started receiving “a lot of that heat.”⁹⁵⁶

B. Similar to JUUL, Puff Bar Marketed and Profited from a Portfolio of Non-Traditional Flavors

As described in Part III above, non-traditional flavored pods were central to JUUL’s rise in the e-cigarette market, and the company viewed flavors as important because they encouraged customer use and cemented loyalty.⁹⁵⁷ Since its 2019 launch, Puff Bar has offered a portfolio of non-traditional flavors, including numerous flavors that have been associated with youth appeal.⁹⁵⁸ For its 2021 relaunch, Puff Bar

⁹⁵¹ Beltran Interview (Sept. 28, 2023).

⁹⁵² *Id.*

⁹⁵³ *Id.*; Minas Interview (Sept. 27, 2023).

⁹⁵⁴ Kar-Hai Chu et al., *Puff Bars, Tobacco Policy Evasion, and Nicotine Dependence: Content Analysis of Tweets*, 24(3) J. MED. INTERNET RSCH. e27894 at 2 (2022).

⁹⁵⁵ Minas Interview (Sept. 27, 2023).

⁹⁵⁶ Beltran Interview (Sept. 28, 2023).

⁹⁵⁷ See *supra* Part III, Section II.

⁹⁵⁸ See *Collection: Puff Bar*, Rsch. into the Impact of Tobacco Advert., STAN. UNIV., <https://tobacco.stanford.edu/disposables/puff-bar-main/puff-bar/>. Product flavors included: Pomegranate,

continued to offer products in a variety of non-traditional flavors.⁹⁵⁹ Puff Bar’s non-traditional flavors, such as Banana Ice, Lychee Ice, and Cool Mint, dominated company sales compared to Menthol and Tobacco flavors.⁹⁶⁰ According to Mr. Beltran, these flavors were “extremely important” to the company’s business model and the company expanded its flavor portfolio due to market demand.⁹⁶¹ While the company’s variety of flavors retained customers and cemented brand loyalty,⁹⁶² its flavors appealed to youth and young adults.⁹⁶³

1. Puff Bar’s Co-CEOs Said that Non-Traditional Flavors Were “Critical” and “Extremely Important” to the Company’s Business Model

According to Puff Bar’s co-CEOs, Puff Bar’s variety of flavors were vital to the company’s business model. Mr. Minas explained to the Subcommittee that flavors were “critical” and that “flavors and Puff Bar go hand-in-hand.”⁹⁶⁴ He also said that flavors are the “biggest selling point” for e-cigarettes aside from the potential health benefits compared to smoking cigarettes.⁹⁶⁵ Mr. Beltran told the Subcommittee that flavors were “extremely important” to Puff Bar and customers liked its products for its flavors.⁹⁶⁶ Mr. Beltran explained that Puff Bar offered a variety of flavors to provide consumers “choice” and “different options.”⁹⁶⁷ Similarly, Mr. Minas said that the company’s portfolio of flavors was intended to “cater” to “different palate[s].”⁹⁶⁸ However, flavors also helped the company retain customers. Mr. Minas believed that having only one flavor would have limited the number of Puff Bar customers, and added that if a customer “got tired of that one flavor” there was a chance that the customer would return to using cigarettes.⁹⁶⁹ Mr. Beltran believed the company’s flavors cemented brand loyalty, and that if customers liked Puff Bar’s flavors, then they would “continue to stick with our brand compared to another brand on the market.”⁹⁷⁰

Additionally, Puff Bar’s co-CEOs acknowledged that its flavors resulted in higher revenue for the company. Mr. Beltran stated that Puff Bar’s portfolio of flavors was “definitely” a business enabler that drove company revenue and explained that if the company only sold Tobacco flavor, the company “would definitely take even more of a decline” than it already had.⁹⁷¹ Mr. Minas explained that the goal of offering non-

Sour Apple, Blueberry Ice, Blueberry, Pink Lemonade, Grape, Banana Ice, Pineapple Lemonade, O.M.G., Lush, Watermelon, Lychee Ice, Blue Razz, Strawberry, Mango, and Cool Mint.

⁹⁵⁹ “Evo Brands LLC, Product Identification Training Guide, June 2, 2022”.

⁹⁶⁰ “PVG2 FTC Inquiry DataFile 1 4895-6439-3295 v.1”; “Puff Sales 2022”.

⁹⁶¹ Beltran Interview (Sept. 28, 2023).

⁹⁶² *Id.*; Minas Interview (Sept. 27, 2023).

⁹⁶³ *See 2021 E-cigarette Use Among Middle and High School Students, supra note 82; 2022 E-cigarette Use Among Middle and High School Students, supra note 84.*

⁹⁶⁴ Minas Interview (Sept. 27, 2023).

⁹⁶⁵ *Id.*

⁹⁶⁶ Beltran Interview (Sept. 28, 2023).

⁹⁶⁷ *Id.*

⁹⁶⁸ Minas Interview (Sept. 27, 2023).

⁹⁶⁹ *Id.*

⁹⁷⁰ Beltran Interview (Sept. 28, 2023).

⁹⁷¹ *Id.*

traditional flavors was “not to just make more profit” but to convert more cigarette users to e-cigarettes.⁹⁷² However, he noted that Puff Bar’s “determination to convert more people” from cigarettes to e-cigarettes with its flavors resulted in higher revenue for the company.⁹⁷³

Furthermore, due to the significant role of flavors in its business model, Puff Bar introduced new flavors and expanded its flavor portfolio based on market demand. In 2021, when Puff Bar relaunched, the company assessed the flavors being offered by its competitors.⁹⁷⁴ Puff Bar wanted to maintain the “standard baseline” flavors and flavors associated with Puff Bar such as Banana Ice and Cool Mint, but also wanted to offer new flavors that would “pique people’s interest.”⁹⁷⁵ The market was also shifting to “more unique blends of flavors.”⁹⁷⁶ As a result, Puff Bar offered new flavors, including Lemon Ice, Pineapple Mango Orange, Strawberry Kiwi, and Cran Lemon.⁹⁷⁷ However, before introducing these new flavors, Puff Bar failed to conduct any studies or surveys regarding user preference for these flavors, including the potential appeal of these flavors to youth and young adults. Instead, Mr. Minas said the company asked customers and friends for input on new flavors.⁹⁷⁸

2. Non-Traditional Flavors Dominated Puff Bar Sales

Acknowledging that non-traditional flavors were important to the company, Mr. Minas and Mr. Beltran relaunched Puff Bar with disposable e-cigarettes in a variety of flavors, including fruit, Mint, Menthol, and Tobacco. For Puff Bar’s four products—Puff Max, Puff Plus, Puff Flow, and Puff Bar—the majority of the offered flavors were fruit.⁹⁷⁹ In addition to fruit flavors, Puff Bar offered Cool Mint for all products and Menthol and Tobacco for all products except the Puff Max.⁹⁸⁰

Puff Max	Puff Plus	Puff Flow	Puff Bar
Aloe Grape	Aloe Grape	Aloe Grape	Banana Ice
Banana Ice	Aloe Mango Berry	Aloe Mango Melon	Blue Razz
Blue Razz	Banana Ice	Ice	Blueberry Ice
Pomegranate Ice	Blue Razz	Banana Ice	Cool Mint
Blueberry Ice	Blueberry Ice	Blue Razz	Grape
Clear	Clear	Blueberry Ice	Guava Ice
Cool Mint	Cool Mint	Cool Mint	Lemon Ice
Mango Peach	Guava Ice	Cran Lemon	Lush
Watermelon	Lemon Ice	Guava Ice	Lychee Ice
Melon Kiwi Ice	Lemon Razz	Kiwi Strawberry	Mango

⁹⁷² Minas Interview (Sept. 27, 2023).

⁹⁷³ *Id.*

⁹⁷⁴ *Id.*

⁹⁷⁵ *Id.*; Beltran Interview (Sept. 28, 2023).

⁹⁷⁶ Beltran Interview (Sept. 28, 2023).

⁹⁷⁷ *Id.*; Minas Interview (Sept. 27, 2023).

⁹⁷⁸ Minas Interview (Sept. 27, 2023).

⁹⁷⁹ “Evo Brands LLC, Product Identification Training Guide, June 2, 2022”.

⁹⁸⁰ *Id.*

Mystery Pineapple Mango Orange Strawberry Apple Peach	Lush Lychee Ice Mango Menthol Mixed Berries Mystery Peach Ice Straw Watermelon Strawberry Banana Tobacco Watermelon	Lemon Ice Lemon Razz Lychee Ice Mango Menthol Mystery Passion fruit Peach Ice Peach Mango Pineapple Tangerine Ice Tobacco Watermelon	Melon Ice Menthol Peach Ice Strawberry Strawberry Banana Tobacco Watermelon
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Figure 23: Puff Bar Products and Flavors⁹⁸¹

Internal sales figures reveal that Puff Bar’s Cool Mint and fruit flavors dominated company sales. Among the 52 products and flavors Puff Bar offered in 2021, the top five products and flavors in terms of dollar sales for units sold were Puff Plus-Banana Ice, Puff Plus-Cool Mint, Puff Flow-Cool Mint, Puff Flow-Aloe Grape, and Puff Plus-Lush.⁹⁸² These five products accounted for \$1.4 million in sales—over 26 percent of the \$5.3 million total sales in 2021.⁹⁸³ In terms of total devices sold, Puff Plus-Banana Ice, Puff Plus-Cool Mint, Puff Plus-Lush, Puff Plus-Strawberry Banana, and Puff Plus-Blueberry Ice were the top selling products and flavors totaling over 275,100 units—28 percent of the nearly 959,500 total units sold that year.⁹⁸⁴ In contrast, Puff Bar’s Menthol and Tobacco products had much lower demand: Puff Flow-Menthol, Puff Plus-Menthol, and Puff Bar-Tobacco products contributed to \$228,896 in sales and over 33,000 units sold—only four percent of total sales and three percent of total units sold.⁹⁸⁵

In 2022, Puff Bar expanded its product and flavor portfolio and offered 157 products and flavors. Cool Mint and Blueberry Ice continued to be among the top popular flavors along with fruit flavors. In terms of sales, the top five products and flavors were Puff Max-Cool Mint, Puff Flow-Lychee Ice, Puff Max-Blueberry Ice, Puff Max-Mango Peach Watermelon, and Puff Max-Pineapple Mango Orange.⁹⁸⁶ These top five products and flavors totaled approximately \$482,905 in sales—nearly 21 percent of total sales (\$2.3 million).⁹⁸⁷ In terms of total devices sold, the top five products and flavors—Puff Plus-Cool Mint, Puff Flow-Lychee Ice, Puff Max-Cool Mint, Puff Flow-Blue Razz, Puff Max-Blueberry Ice—accounted for over 65,600 units sold, nearly 18 percent

⁹⁸¹ *Id.*
⁹⁸² The characterizing flavor for Lush was Watermelon Ice. Minas Interview (Sept. 27, 2023); “PVG2 FTC Inquiry DataFile 1 4895-6439-3295 v.1”.
⁹⁸³ “PVG2 FTC Inquiry DataFile 1 4895-6439-3295 v.1”.
⁹⁸⁴ *Id.*
⁹⁸⁵ *Id.*
⁹⁸⁶ “Puff Sales 2022”.
⁹⁸⁷ *Id.*

of the total units sold (366,034).⁹⁸⁸ Compared to 2021 when the company only offered two Menthol products and one Tobacco product, Puff Bar added Menthol to the Puff Bar and Puff Flow, Tobacco for the Puff Flow and Plus, and two Tobacco flavors for the Puff Flow. Despite offering more e-cigarettes in Menthol and Tobacco flavors, the eight products accounted for only 2.4 percent (\$55,340) of total sales.⁹⁸⁹ Similar to the previous year, the company’s Menthol and Tobacco products accounted for three percent (11,140 units) of total units sold.⁹⁹⁰

2021 Sales	2021 Devices	2022 Sales	2022 Devices
1. Puff Plus - Banana Ice	1. Puff Plus - Banana Ice	1. Puff Max - Cool Mint	1. Puff Plus - Cool Mint
2. Puff Plus - Cool Mint	2. Puff Plus - Cool Mint	2. Puff Flow - Lychee Ice	2. Puff Flow - Lychee Ice
3. Puff Flow - Cool Mint	3. Puff Plus - Lush	3. Puff Max - Blueberry Ice	3. Puff Max - Cool Mint
4. Puff Flow - Aloe Grape	4. Puff Plus - Strawberry Banana	4. Puff Max - Mango Peach	4. Puff Flow - Blue Razz
5. Puff Plus - Lush	5. Puff Plus - Blueberry Ice	5. Puff Max - Pineapple Mango Orange	5. Puff Max - Blueberry Ice
15. Puff Flow - Menthol	21. Puff Flow - Menthol	42. Puff Plus - Menthol	40. Puff Plus - Menthol
27. Puff Plus - Menthol	27. Puff Plus - Menthol	44. Puff Flow - Menthol	48. Puff Flow - Menthol
42. Puff Bar - Tobacco	42. Puff Bar - Tobacco	55. Puff Plus - Tobacco 800	52. Puff Plus - Tobacco 800
		57. Puff Plus - Tobacco	58. Puff Plus - Tobacco
		61. Puff Bar - Menthol	61. Puff Bar - Menthol
		63. Puff Bar - Tobacco	62. Puff Bar - Tobacco
		86. Puff Flow - Tobacco	75. Puff Flow - Tobacco
		98. Puff Flow - Menthol	95. Puff Flow - Menthol 1800

Figure 24: Top Five Most Popular Puff Bar Flavors and Ranking of Puff Bar Menthol and Tobacco Products in 2021 and 2022⁹⁹¹

Mr. Minas and Mr. Beltran were aware that Banana Ice, with characterizing flavors of banana and menthol, was Puff Bar’s most popular flavor and, according to Mr.

⁹⁸⁸ *Id.*

⁹⁸⁹ *Id.*

⁹⁹⁰ *Id.*

⁹⁹¹ *Id.*; “PVG2 FTC Inquiry DataFile 1 4895-6439-3295 v.1”.

Beltran, the company's "bestseller."⁹⁹² Historically, the banana flavor was an unpopular e-cigarette flavor, but when Cool Clouds launched the Banana Ice flavor for Puff Bar products, the company limited the number of devices and made it "very hard to get."⁹⁹³ This perceived scarcity contributed to Banana Ice's popularity and it became Puff Bar's "number one flavor."⁹⁹⁴ Knowing that Banana Ice was Puff Bar's most popular flavor, the co-CEOs decided to continue offering the flavor when they relaunched the company in 2021.⁹⁹⁵ However, as other e-cigarette companies followed Puff Bar's lead and introduced their own banana-flavored products, Mr. Minas believed Banana Ice became a less popular flavor for Puff Bar in 2022.⁹⁹⁶ Similar to Banana Ice, Mr. Minas and Mr. Beltran knew that Lychee Ice, the second most popular flavor in 2022, was a new flavor introduced and popularized by Cool Clouds's Puff Bar.⁹⁹⁷ Based on its popularity, they decided to offer the Lychee Ice flavor when they acquired the company, and Lychee Ice continued to be a popular flavor for the company.⁹⁹⁸ Mr. Minas told the Subcommittee that Banana Ice and Lychee Ice became "synonymous" with the Puff Bar brand, and the company is still known today for these two flavors.⁹⁹⁹ Cool Mint was another popular flavor in 2021 and 2022, and Mr. Minas said that generally, the mint flavor had been a "consistent" and "top" e-cigarette flavor in the industry.¹⁰⁰⁰

3. Puff Bar Knew Flavors Appealed to Youth and Young Adults, but Emphasized the Importance of Flavors to Adults, Relying on Anecdotal Evidence

Puff Bar's co-CEOs each told the Subcommittee that they were aware of the NYTS results and knew flavors appealed to youth and young adults.¹⁰⁰¹ Despite this awareness, the company continued to offer a wide variety of fruit and mint flavors. The co-CEOs took the position that flavors help smokers transition away from cigarettes.¹⁰⁰² Mr. Minas told the Subcommittee that "flavors are probably the biggest incentive to transition from cigarettes to vape products" and the biggest "selling point" for traditional cigarettes users to switch to e-cigarettes.¹⁰⁰³ He also explained that "flavors are an important consideration for all age groups" otherwise "we would all eat flavorless food and flavorless drinks."¹⁰⁰⁴

⁹⁹² Minas Interview (Sept. 27, 2023); Beltran Interview (Sept. 28, 2023).

⁹⁹³ Minas Interview (Sept. 27, 2023); Beltran Interview (Sept. 28, 2023). Mr. Minas stated that he "didn't own Puff at the time" and did not know how the previous owners of Puff Bar decided on the Banana Ice flavor. Minas Interview (Sept. 27, 2023).

⁹⁹⁴ Minas Interview (Sept. 27, 2023).

⁹⁹⁵ *Id.*; Beltran Interview (Sept. 28, 2023).

⁹⁹⁶ Minas Interview (Sept. 27, 2023).

⁹⁹⁷ *Id.*; Beltran Interview (Sept. 28, 2023).

⁹⁹⁸ Minas Interview (Sept. 27, 2023).

⁹⁹⁹ *Id.*; Beltran Interview (Sept. 28, 2023).

¹⁰⁰⁰ Minas Interview (Sept. 27, 2023).

¹⁰⁰¹ *Id.*; Beltran Interview (Sept. 28, 2023).

¹⁰⁰² Minas Interview (Sept. 27, 2023); Beltran Interview (Sept. 28, 2023).

¹⁰⁰³ Minas Interview (Sept. 27, 2023).

¹⁰⁰⁴ *Id.*

Similarly, Mr. Beltran believed flavors “add[ed] to the satisfaction” and “enjoyment” of using e-cigarette products.¹⁰⁰⁵ He pointed to Puff Bar sales data showing that Tobacco and Menthol were among Puff Bar’s least popular flavors.¹⁰⁰⁶ He believed Tobacco was an unpopular Puff Bar flavor because cigarette users are inclined to choose a product that provides the same nicotine satisfaction without the “negative flavor” of tobacco.¹⁰⁰⁷ Mr. Beltran also told the Subcommittee that reports of youth use of flavored e-cigarettes do not “supersede the adults” that are using flavored e-cigarette products.¹⁰⁰⁸

Mr. Minas and Mr. Beltran both stated to the Subcommittee that Puff Bar’s flavors helped adult smokers switch from cigarettes to e-cigarettes, but they based these claims on anecdotal evidence, such as emails and conversations with Puff Bar customers.¹⁰⁰⁹ According to the co-CEOs, Puff Bar never studied the impact of its products on user cessation of combustible cigarettes due to the costs associated with conducting these studies.¹⁰¹⁰

C. Puff Bar Was Influenced by JUUL’s “Simple” Branding

Puff Bar was influenced by JUUL’s brand marketing. Mr. Minas told the Subcommittee that he “liked what JUUL was doing” and how JUUL had “kept everything very clean and very simple.”¹⁰¹¹ Even though Puff Bar was JUUL’s competitor, Puff Bar “took a lot of influence from what, [JUUL was] doing and what was at the time working for [JUUL].”¹⁰¹² Influenced by JUUL’s “simplicity” and “clean” branding, Puff Bar simplified the number of flavors it offered.¹⁰¹³ When Mr. Minas and Mr. Beltran acquired Puff Bar, the company had over 50 different flavors across its various devices.¹⁰¹⁴ For example, Puff Bar offered Pink Lemonade and O.M.G.¹⁰¹⁵ Puff Bar looked at JUUL’s “simplistic approach,” narrowed the number of flavors offered, and changed “crazy flavor names” like Strawberry Lemon Sorbet because “simple was the way to go.”¹⁰¹⁶

JUUL also influenced Puff Bar’s decision to introduce new flavors. As explained above, Puff Bar introduced new flavors, such as Lemon Ice and Pineapple Mango Orange.¹⁰¹⁷ Mr. Beltran explained that Puff Bar was “trying to be like a JUUL” where JUUL was “on the sidelines in their own game” and not competing with other products. He told the Subcommittee that Puff Bar was trying to emulate JUUL and be a disposable e-cigarette brand offering the “biggest nows”—the most popular products at

¹⁰⁰⁵ Beltran Interview (Sept. 28, 2023).

¹⁰⁰⁶ *Id.*; “PVG2 FTC Inquiry DataFile 1 4895-6439-3295 v.1”; “Puff Sales 2022”.

¹⁰⁰⁷ Beltran Interview (Sept. 28, 2023).

¹⁰⁰⁸ *Id.*

¹⁰⁰⁹ *Id.*; Minas Interview (Sept. 27, 2023).

¹⁰¹⁰ Minas Interview (Sept. 27, 2023); Beltran Interview (Sept. 28, 2023).

¹⁰¹¹ Minas Interview (Sept. 27, 2023).

¹⁰¹² *Id.*

¹⁰¹³ *Id.*

¹⁰¹⁴ Beltran Interview (Sept. 28, 2023).

¹⁰¹⁵ *Id.*; Minas Interview (Sept. 27, 2023).

¹⁰¹⁶ Minas Interview (Sept. 27, 2023); Beltran Interview (Sept. 28, 2023).

¹⁰¹⁷ See *supra* Part V, Section III.B.

the time.¹⁰¹⁸ Based on market demand for “unique blends of flavors,” Puff Bar introduced new flavors.¹⁰¹⁹

D. Puff Bar Adopted JUUL’s Five Percent Nicotine Concentration

Before JUUL released e-cigarettes with a five percent nicotine concentration in 2015, most e-cigarette products came in one to two percent concentrations.¹⁰²⁰ JUUL claimed that the five percent concentration was approximately equivalent to the amount of nicotine in one pack of cigarettes.¹⁰²¹ According to a 2019 study, JUUL’s decision drove a “widespread rush” of companies to increase their own nicotine concentrations and created “a nicotine arms race.”¹⁰²² By 2019, e-cigarette nicotine levels reached five to seven percent.¹⁰²³ JUUL achieved a high nicotine concentration by using “nicotine salts,” a salt that is formed when an acid is mixed in a solution with free-base nicotine.¹⁰²⁴ Nicotine salts can mask the bitter taste of nicotine.¹⁰²⁵

Puff Bar adopted JUUL’s five percent nicotine level from the beginning. Cool Clouds introduced Puff Bar e-cigarettes with a five percent nicotine concentration in 2019.¹⁰²⁶ According to Mr. Minas, at the time, five percent was what the “industry standard” had become and the industry “piggybacked off” of the level of JUUL pods.¹⁰²⁷ When Puff Bar relaunched in 2021, the company continued offering products with five percent nicotine, or 50 mg/ml in each e-cigarette, only this time in synthetic form.¹⁰²⁸ Mr. Beltran stated that Puff Bar “followed a lot of what JUUL did” in relation to nicotine levels and decided to stick with JUUL’s five percent nicotine concentration.¹⁰²⁹

Before offering a five percent nicotine product, Puff Bar failed to conduct any research or studies on this specific nicotine concentration and nicotine dependency. Mr. Minas said that Puff Bar had plans to conduct these studies, but the company was

¹⁰¹⁸ Beltran Interview (Sept. 28, 2023).

¹⁰¹⁹ *Id.*

¹⁰²⁰ Robert Jackler & Divya Ramamurthi, *Nicotine Arms Race: JUUL and the high-nicotine product market*, 28 TOBACCO CONTROL 623, 623 (2019).

¹⁰²¹ See Judith Prochaska et al., *Nicotine delivery and cigarette equivalents from vaping a JUUL pod*, 31 TOBACCO CONTROL E88-E93 (2022).

¹⁰²² Jackler & Ramamurthi, *supra* note 1020; Michael Nedelman & Roni Selig, *JUUL ramped up nicotine levels, and competitors followed, study says*, CNN (Feb. 7, 2019), <https://www.cnn.com/2019/02/07/health/juul-nicotine-arms-race-study/index.html>.

¹⁰²³ Jackler & Ramamurthi, *supra* note 1020.

¹⁰²⁴ Arit Havanko et al., *Characterization of Nicotine Salts in 23 Electronic Cigarette Refill Liquids*, 22(7) NICOTINE & TOBACCO RSCH. 1239, 1239-40 (2020); Adam Leventhal et al., *Effect of Exposure to e-Cigarettes with Salt vs Free-base Nicotine on the Appeal and Sensory Experience of Vaping: A Randomized Clinical Trial*, 4(1) JAMA NETWORK OPEN e2032757, e2032757 (2021).

¹⁰²⁵ Nedelman & Selig, *supra* note 1022.

¹⁰²⁶ Minas Interview (Sept. 27, 2023). Cool Clouds also offered the Puff Bar e-cigarette with a 2 percent nicotine concentration, but the product “never really sold that well.” Beltran Interview (Sept. 28, 2023).

¹⁰²⁷ Minas Interview (Sept. 27, 2023).

¹⁰²⁸ *Id.*

¹⁰²⁹ Beltran Interview (Sept. 28, 2023).

“running super lean” and these studies were “time consuming” and “very costly.”¹⁰³⁰ Mr. Beltran also cited limited resources, including time and money, and noted that there were existing studies on nicotine but claimed that “the motivation was very much there” to conduct these studies.¹⁰³¹ Similar to JUUL, Puff Bar also used nicotine salts. Mr. Beltran explained that JUUL was “one of the pioneers” of nicotine salts, and Puff Bar used a salt-based synthetic nicotine for its products to offer a smooth “nicotine hit” and cigarette-like experience.¹⁰³²

E. Although Puff Bar Learned from JUUL’s Mistakes and Avoided Certain Marketing Efforts, the Company Knew That Its Success Was Based on Brand Notoriety and User-Generated Content

Puff Bar studied JUUL’s marketing and advertising mistakes and avoided efforts that could potentially put the company “into the crossfire,” such as paid advertisements, large parties with celebrities, and using social media for marketing purposes.¹⁰³³ Instead of engaging in traditional marketing efforts, the company relied on brand notoriety. Mr. Beltran explained that Puff Bar became the “Kleenex of disposables”—in other words, not just a brand but a noun synonymous with disposable e-cigarettes.¹⁰³⁴ Mr. Minas said that the company relied on this brand notoriety for its 2021 relaunch. Puff Bar also benefited from user-generated content on social media. At one point, Puff Bar-related hashtags had nearly one billion impressions.¹⁰³⁵

1. Puff Bar Learned from JUUL’s Mistakes and Chose Not to Employ Certain Marketing Efforts

Puff Bar studied JUUL’s marketing and advertising mistakes in choosing not to employ certain marketing and advertising techniques. According to Mr. Minas, Puff Bar saw JUUL as an “older brother.”¹⁰³⁶ He also said “everyone” put JUUL on a pedestal and then saw the “negative” actions that “came to the light.”¹⁰³⁷ Mr. Beltran told the Subcommittee that Puff Bar studied JUUL’s marketing tactics and concluded that the “only studying there was, like, don’t do it.”¹⁰³⁸ He explained that JUUL’s marketing tactics “ended up coming to bite them in the butt,” which Puff Bar “always kept in the back of our heads.”¹⁰³⁹ Puff Bar tried to avoid any marketing that could potentially put them “into the crossfire” like JUUL.¹⁰⁴⁰ These efforts included avoiding large parties

¹⁰³⁰ Minas Interview (Sept. 27, 2023).

¹⁰³¹ Beltran Interview (Sept. 28, 2023).

¹⁰³² *Id.*

¹⁰³³ *Id.*

¹⁰³⁴ *Id.*

¹⁰³⁵ *Id.*

¹⁰³⁶ Minas Interview (Sept. 27, 2023).

¹⁰³⁷ *Id.*

¹⁰³⁸ Beltran Interview (Sept. 28, 2023).

¹⁰³⁹ *Id.*

¹⁰⁴⁰ *Id.*

with celebrities, collaborations with individuals, paid advertisements, and the placement of banners or posters in “high traffic” areas.¹⁰⁴¹

In addition, Puff Bar witnessed JUUL “running into issues” with the age of models used in marketing campaigns, and Puff Bar stopped using models in email marketing campaigns after its 2021 relaunch.¹⁰⁴² Because JUUL received “so much flak” for its social media use, Puff Bar “didn’t even go down that road” of using social media or “doing any outward marketing.”¹⁰⁴³

Seeing the criticism JUUL’s marketing and advertising received, Puff Bar allocated minimal resources to marketing and advertising, and the co-CEOs stated that Puff Bar did not have a marketing plan or strategy for its products.¹⁰⁴⁴ According to Mr. Minas, Puff Bar “did little to no marketing” and spent “a little bit, almost zero” on traditional marketing and advertisements.¹⁰⁴⁵ According to internal records, Puff Bar spent over \$448,000 on marketing and advertising in 2021 and 2022.¹⁰⁴⁶ The majority of this spending went toward “marketing events” or trade shows the company attended but also included expenditures for email marketing, point-of-sale advertising, and operation of the company’s website.¹⁰⁴⁷

a. Puff Bar Received Similar Criticism as JUUL for Appealing to Youth in Two 2020 Email Marketing Campaigns

Two email marketing campaigns by Puff Bar received similar criticism as JUUL for appealing to youth. Although Mr. Minas and Mr. Beltran were not co-CEOs of Puff Bar at the time of these marketing campaigns, they were responsible for promoting Puff Bar products on PuffBar.com under the 2020 license agreement and sent out these two email campaigns.¹⁰⁴⁸ Mr. Minas and Mr. Beltran used email marketing campaigns to promote Puff Bar products and retained a marketing company called Aavya—“a freelancer overseas”—to create these campaigns.¹⁰⁴⁹ One of these campaigns, which Puff Bar distributed during the COVID-19 pandemic in 2020, was called “solo break” and stated, “Stay sane with Puff Bar this solo-break. We know you’ll love it. It’s the

¹⁰⁴¹ Minas Interview (Sept. 27, 2023). See also “PVG2 FTC Inquiry Datafile No. 2 4881-2957-2176 v.1 1.xlsx”.

¹⁰⁴² In email campaigns for Puff Bar products sold by Cool Clouds, Puff Bar used models in its email campaigns. When PVG2/EVO Brands took over Puff Bar in 2021, it did not use models in Puff Bar email campaigns. Beltran Interview (Sept. 28, 2023).

¹⁰⁴³ *Id.*

¹⁰⁴⁴ *Id.*; Minas Interview (Sept. 27, 2023). Because Puff Bar is no longer a nicotine company selling nicotine products, Mr. Beltran stated that the company is not bound by the restrictions for nicotine companies and is determining its marketing efforts going forward, including offering merchandise such as Puff Bar branded apparel. Beltran Interview (Sept. 28, 2023).

¹⁰⁴⁵ Minas Interview (Sept. 27, 2023).

¹⁰⁴⁶ “2021 Marketing and Advertising Spend”; “2022 Marketing and Advertising Spend”

¹⁰⁴⁷ “2021 Marketing and Advertising Spend”; “2022 Marketing and Advertising Spend”; Minas Interview (Sept. 27, 2023).

¹⁰⁴⁸ PUFFBAR00000012-16; Minas Interview (Sept. 27, 2023); Beltran Interview (Sept. 28, 2023).

¹⁰⁴⁹ Beltran Interview (Sept. 28, 2023); Nov. 10, 2023 Puff Bar Response.

perfect escape from the back-to-back zoom calls, parental texts, and WFH stress.”¹⁰⁵⁰ The email campaign received criticism for marketing directly to youth during the pandemic with its reference to “parental texts” and an image of a young-looking woman blowing a large cloud of vapor.¹⁰⁵¹

According to Mr. Minas and Mr. Beltran, this email campaign was directed toward adults—Millennials ages 21 to 30—working from home due to the pandemic who, as Mr. Beltran described, had “parents still involved in their lives.”¹⁰⁵² Mr. Minas stated that “parental texts” referenced texts received by parents, but Mr. Beltran, who was responsible for all email marketing campaigns, clarified that “parental texts” meant texts from parents.¹⁰⁵³ Both Mr. Minas and Mr. Beltran acknowledged that the reference to “parental texts” could be misinterpreted and appear to target a younger demographic and the underage population.¹⁰⁵⁴ Mr. Beltran said that he did not recall reviewing this specific email, but he took responsibility for all email campaigns.¹⁰⁵⁵ He also noted that the “biggest problem” was that Aavya did not understand the restrictions around marketing nicotine products.¹⁰⁵⁶ He acknowledged that the company learned from this backlash that it had to be “more careful” with email marketing campaigns.¹⁰⁵⁷

¹⁰⁵⁰ PUFFBAR00000061.

¹⁰⁵¹ See Letter from Raja Krishnamoorthi, Chairman, H. Comm. on Oversight & Reform Subcomm. on Econ. & Consumer Pol’y, to Stephen M. Hahn, Comm’r, U.S. Food & Drug Admin. (June 1, 2020), <https://oversightdemocrats.house.gov/sites/democrats.oversight.house.gov/files/2020-06-01%20RK%20to%20Hahn-%20FDA%20Puff%20Bar%20Products.pdf>; Letter from Meredith Berkman & Dorian Furhman, Co-Founders, Parents Against Vaping e-Cigarettes, to Mitch Zeller, Dir., Ctr. for Tobacco Prods., U.S. Food & Drug Admin. (May 29, 2020), <https://www.parentsagainstvaping.org/fda-letter>.

¹⁰⁵² Minas Interview (Sept. 27, 2023); Beltran Interview (Sept. 28, 2023).

¹⁰⁵³ Minas Interview (Sept. 27, 2023); Beltran Interview (Sept. 28, 2023).

¹⁰⁵⁴ Minas Interview (Sept. 27, 2023); Beltran Interview (Sept. 28, 2023). Mr. Beltran stated that the goal of email campaigns is to convert to purchases, and because underage purchasers would not have been able to check out on the company’s website due to its age verification system, this email campaign would have been a “horrible waste of time” to target underage users. Beltran Interview (Sept. 28, 2023).

¹⁰⁵⁵ Beltran Interview (Sept. 28, 2023).

¹⁰⁵⁶ *Id.*

¹⁰⁵⁷ *Id.*



Figure 25: 2020 Puff Bar “Solo Break” Email Campaigns¹⁰⁵⁸

Another email campaign with the “solo break” theme stated, “Nothing can take away the sunshine or your individuality. This spring break, sit back and relax solo.”¹⁰⁵⁹ Mr. Minas and Mr. Beltran each claimed that the email campaign targeted college students over age 21.¹⁰⁶⁰ Mr. Beltran stated that he did not have any concerns before the email campaign was distributed on how the reference to spring break or the age perception of the models in the email could be geared towards a younger demographic.¹⁰⁶¹ Mr. Beltran approved the campaign but admitted that he “overlooked a lot of things” and this was “a complete oversight” on his end.¹⁰⁶² He explained that he put his trust in the marketing company and gave it “a lot of the reins” on launching emails because the company was a “reputable company” and had worked for “big brands.”¹⁰⁶³ He added that there was an urgency and pressure to send out these initial email campaigns, and “in hindsight” he would have “never sent this email.”¹⁰⁶⁴

After these “solo break” email campaigns received public criticism for targeting youth, Mr. Minas said that Puff Bar implemented additional “checks and balances” for its email marketing campaigns.¹⁰⁶⁵ For example, more than one Puff Bar employee would

¹⁰⁵⁸ PUFFBAR00000060-61.

¹⁰⁵⁹ PUFFBAR00000060.

¹⁰⁶⁰ Minas Interview (Sept. 27, 2023).

¹⁰⁶¹ Beltran Interview (Sept. 28, 2023).

¹⁰⁶² *Id.*

¹⁰⁶³ *Id.*

¹⁰⁶⁴ *Id.*

¹⁰⁶⁵ Minas Interview (Sept. 27, 2023).

review and approve email campaigns, and, as mentioned above, Puff Bar stopped using models in campaigns.¹⁰⁶⁶ Additionally, email campaigns for the 2021 relaunch of the Puff Bar brand were “extremely different.”¹⁰⁶⁷ The company took a “minimalistic approach, nothing too flashy” and focused on the products themselves in email marketing campaigns.¹⁰⁶⁸

2. Puff Bar Relied on Brand Notoriety Instead of Traditional Marketing Efforts

Puff Bar had become so popular by the time it relaunched in 2021 that the company did not need to undertake traditional marketing efforts, instead relying on “brand notoriety.”¹⁰⁶⁹ When Cool Clouds initially launched Puff Bar in 2019, JUUL and other cartridge-based e-cigarettes dominated the market, and disposable e-cigarettes were becoming popular.¹⁰⁷⁰ According to Mr. Beltran, Puff Bar was the only disposable e-cigarette on the market at a large scale at the time of its launch, which led Puff Bar to become the “Kleenex of disposables”—in other words, not just a brand but a noun synonymous with disposable e-cigarettes.¹⁰⁷¹ Mr. Beltran explained that other disposable e-cigarettes are called “puff bars,” and that from a brand perspective, “that notoriety is great.”¹⁰⁷² Mr. Minas told the Subcommittee that Puff Bar “relied a lot more on brand notoriety” when relaunching due to the “red tape” surrounding tobacco marketing and seeing the negative feedback JUUL received for its marketing.¹⁰⁷³

Furthermore, Puff Bar learned from the mistakes JUUL made with its social media use and maintained a limited presence on social media. Puff Bar has accounts on Twitter, Instagram, and TikTok.¹⁰⁷⁴ Puff Bar has never posted on Twitter, and the company’s accounts on Instagram (@puffbar) and TikTok (@puff_bar_official) had approximately 2,519 followers and 2,962 followers, respectively, as of September 2023.¹⁰⁷⁵ Mr. Beltran told the Subcommittee that Puff Bar’s use of social media had “never been a priority” and the company never had a social media strategy.¹⁰⁷⁶ Puff Bar used its social media accounts to focus on “brand presence” and as a channel for

¹⁰⁶⁶ *Id.*; Beltran Interview (Sept. 28, 2023).

¹⁰⁶⁷ Beltran Interview (Sept. 28, 2023).

¹⁰⁶⁸ *Id.*

¹⁰⁶⁹ Minas Interview (Sept. 27, 2023).

¹⁰⁷⁰ Majmundar et al., *supra* note 888; Megan Diaz et al., *Bigger, stronger and cheaper: Growth in e-cigarette market driven by disposable devices with more e-liquid, higher nicotine concentration and declining prices*, TOBACCO CONTROL (Aug. 3, 2023), <https://tobaccocontrol.bmj.com/content/tobaccocontrol/early/2023/08/02/tc-2023-058033.full.pdf>; TRUTH INITIATIVE, *Bigger, stronger, and cheaper: Disposable e-cigarettes have more nicotine and are more accessible than ever* (Aug. 9, 2023), <https://truthinitiative.org/research-resources/emerging-tobacco-products/bigger-stronger-and-cheaper-disposable-e-cigarettes>.

¹⁰⁷¹ Beltran Interview (Sept. 28, 2023).

¹⁰⁷² *Id.*

¹⁰⁷³ Minas Interview (Sept. 27, 2023).

¹⁰⁷⁴ *Id.*; June 16, 2023 Puff Bar Response; Beltran Interview (Sept. 28, 2023). Puff Bar obtained its Instagram account @puffbar in August 2022 from a “squatter” who had ownership of the account. Minas Interview (Sept. 27, 2023).

¹⁰⁷⁵ “IMG_9770”; “IMG_6858”.

¹⁰⁷⁶ Beltran Interview (Sept. 28, 2023).

product announcements.¹⁰⁷⁷ For example, Puff Bar’s first Instagram post on August 15, 2022, was a picture of the company’s logo and the caption, “Theres [sic] a reason we call everything a Puff Bar.”¹⁰⁷⁸

Despite claiming limited use of social media for advertising purposes, Puff Bar used its first post as an Instagram ad that directed users to Puff Bar’s Instagram page.¹⁰⁷⁹ The ad reached over 370,600 Instagram accounts, which made this a “highly engaging ad” for the amount Puff Bar spent.¹⁰⁸⁰ Mr. Beltran also noted that the Instagram ad was successful because the company had “so much notoriety.”¹⁰⁸¹ Similarly, Mr. Beltran explained Puff Bar’s TikTok content “always does really well” due to the brand’s reputation, even if the content is not “too engaging.”¹⁰⁸² As of January 3, 2023, Puff Bar’s Instagram account had been restricted from advertising on the platform.¹⁰⁸³ Meta’s “business account restriction” notice stated that Puff Bar’s account “didn’t comply with our Advertising policies affecting business assets.”¹⁰⁸⁴ Mr. Beltran was unaware of the circumstances that led to this restriction and said that Meta had not provided any specific reason for the account restriction to the company.¹⁰⁸⁵

¹⁰⁷⁷ *Id.*; Minas Interview (Sept. 27, 2023).

¹⁰⁷⁸ “IMG_9793”.

¹⁰⁷⁹ Beltran Interview (Sept. 28, 2023).

¹⁰⁸⁰ *Id.*

¹⁰⁸¹ *Id.*

¹⁰⁸² *Id.*

¹⁰⁸³ “IMG_9157”.

¹⁰⁸⁴ *Id.*

¹⁰⁸⁵ Beltran Interview (Sept. 28, 2023).

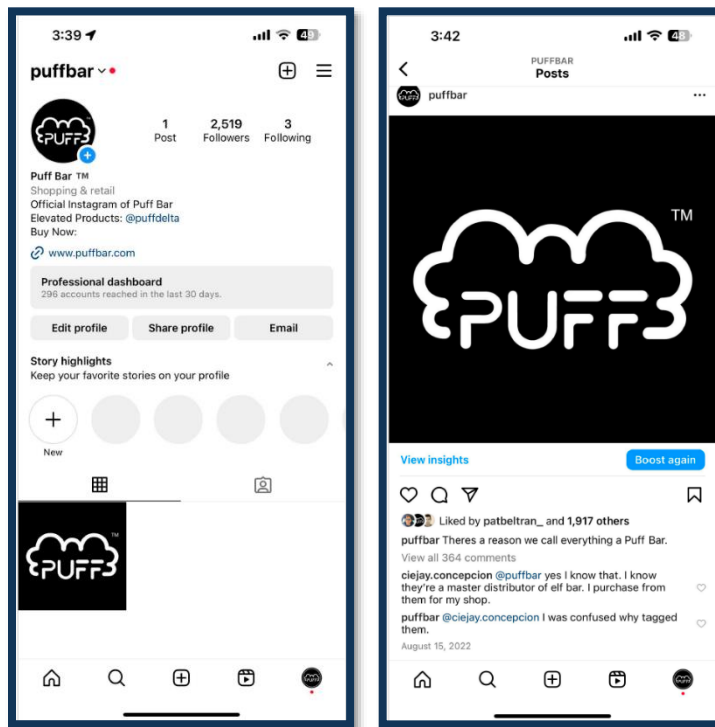


Figure 26: Puff Bar’s @puffbar Instagram Account Page and August 15, 2022 First Post¹⁰⁸⁶

3. Puff Bar Benefited from User-Generated Social Media Content

Similar to JUUL, Puff Bar benefited from user-generated social media content. Mr. Beltran explained that Puff Bar-related content was “extremely popular” on social media, and noted that the “#PuffBar” and “#Puff” hashtags each had over 900 million impressions for a total of one billion impressions.¹⁰⁸⁷ Mr. Beltran told the Subcommittee that “to have a billion impressions of your brand, without you having to pay for it” is “like any company’s dream.”¹⁰⁸⁸

Studies have shown much of the user-generated Puff Bar content targeted youth. For example, a study on user-generated Puff Bar-related content on TikTok collected in July 2020 found that the content revolved around genres that “reflected user experiences and beliefs (skits and stories, shared vaper experiences, videos to show off, crafts) and promoted Puff Bar (product reviews, product unboxing, promotion of Puff Bar), especially to underage users.”¹⁰⁸⁹ Another study that analyzed Puff Bar-related content on TikTok between January 31, 2020 and May 4, 2021, showed that the most prevalent themes included music, flavors, youth/young adults, tobacco use, nicotine

¹⁰⁸⁶ “IMG_9770”; “IMG_9793”.

¹⁰⁸⁷ Beltran Interview (Sept. 28, 2023).

¹⁰⁸⁸ *Id.*

¹⁰⁸⁹ Makayla Morales et al., *#NicotineAddictionCheck: Puff Bar Culture, Addiction Apathy, and Promotion of E-Cigarettes on TikTok*, 19(3) INT’L J. ENV’T RSCH. PUB. HEALTH 1820 (2022).

concentration, and humor.¹⁰⁹⁰ The study noted that “[t]hese e-cigarette-related videos generated millions of views and may be a source of influence for TikTok users,” which generally had a younger user base.¹⁰⁹¹ Yet another study that focused on JUUL- and Puff Bar-related posts on Twitter from July 16, 2019 to August 29, 2020, found that the most prominent topics were flavors, dual use, device features, and youth use.¹⁰⁹²

Mr. Beltran stated that Puff Bar monitored social media for user-generated content “to some degree,” but the vast amount of content and the lack of resources made it “hard” for the company to track.¹⁰⁹³ Mr. Minas stated that the company had not monitored user-generated content related to Puff Bar since he acquired the company in 2021 and cited the growth in popularity of other e-cigarette brands since that time. Because “Puff is no longer the popular brand,” Mr. Minas did not believe users were “making content on Puff.”¹⁰⁹⁴

IV. PUFF BAR KNEW ITS PRODUCTS APPEALED TO YOUTH BUT FAILED TO PREVENT YOUTH PURCHASES AND YOUTH APPEAL OF ITS PRODUCTS

Puff Bar recognized the rise of youth vaping and knew it was popular among youth. Having received communications from concerned parents, Puff Bar was also aware that youth could easily purchase its products at retail stores. Puff Bar did take some efforts to reduce youth appeal. For example, the company discontinued youth appealing flavors, like Cotton Candy, and changed “social” flavor names, such as O.M.G. Puff Bar’s co-CEOs told the Subcommittee that Puff Bar implemented an age verification system on its website and age restricted its social media account, but underage users were still able to skirt these efforts. Despite these limited efforts, Puff Bar did not sufficiently respond to or prevent youth purchases of its products, and its products continued to be popular among youth.

A. Puff Bar Was Aware of the Rise of Youth Vaping and Knew It Was Popular Among Youth

Mr. Minas and Mr. Beltran both told the Subcommittee that they were aware of the rise of youth vaping and the 2020 NYTS results when they purchased Puff Bar in 2021.¹⁰⁹⁵ Mr. Beltran said he believed they had “solutions” and Mr. Minas said they could “solve” the youth vaping issues by purchasing the company and could use age verification and other tracking technology.¹⁰⁹⁶ Mr. Minas told the Subcommittee that he was aware of the youth vaping epidemic and issues with how underage individuals were able to obtain e-cigarette products, but he claimed he was not aware that Puff Bar “had

¹⁰⁹⁰ Jon-Patrick Allem et al., *A thematic analysis of Puff Bar-related content on TikTok*, 58(8) *SUBSTANCE USE & MISUSE* 975, 977 (2023).

¹⁰⁹¹ *Id.* at 978.

¹⁰⁹² Jon-Patrick Allem et al., *Leading Topics in Twitter Discourse on JUUL and Puff Bar Products; Content Analysis*, 23(7) *J. MED. INTERNET RSCH.* e26510 (2021).

¹⁰⁹³ Beltran Interview (Sept. 28, 2023).

¹⁰⁹⁴ Minas Interview (Sept. 27, 2023).

¹⁰⁹⁵ *Id.*; Beltran Interview (Sept. 28, 2023).

¹⁰⁹⁶ Minas Interview (Sept. 27, 2023); Beltran Interview (Sept. 28, 2023).

a problem” with “getting into the hands of youth.”¹⁰⁹⁷ Mr. Minas believed the Puff Bar products he sold after taking over the company were not an “issue with the underage.”¹⁰⁹⁸

Mr. Beltran speculated that “probably the flavors” and the concealability of Puff Bar products made them popular among youth.¹⁰⁹⁹ Mr. Beltran said that he “recognized” that youth vaping was on the rise, but he was “more concerned with the 480,000 deaths per year by cigarette.”¹¹⁰⁰ Mr. Beltran believed that “there are multiple ways” the youth vaping issue could be solved but only “one way to solve the cigarette death issue”—to give smokers “an alternative that is not a cigarette.”¹¹⁰¹ To him, the issue of deaths by cigarette smoking was “more important” than the youth issue, which was “consistently being worked on and solved.”¹¹⁰²

As discussed above, the 2021 and 2022 NYTS found Puff Bar was the most reported brand by middle and high school students. When asked for a reaction to the 2021 NYTS results, Mr. Minas stated that he believed the majority of those students were either smoking Puff Bar products produced in 2020 or counterfeit products, which were “still extremely rampant” in 2021.¹¹⁰³ Similarly, Mr. Beltran noted that Puff Bar had a “huge counterfeit issue” and that students likely confused other disposable e-cigarettes as Puff Bar products.¹¹⁰⁴ Mr. Beltran told the Subcommittee that the company believed it was “going to have a big problem” after this data was released because there was “so much false data around what government officials and people [were] looking at.”¹¹⁰⁵ In addition, Mr. Minas believed the NYTS was not a “fair sample” because Puff Bar relaunched early that year and only through online retail, which “didn’t do well at all.”¹¹⁰⁶ Relatedly, Puff Bar’s marketing plan submitted with its PMTA discussed the 2021 NYTS and cited “limited Puff product sales figures” in 2021.¹¹⁰⁷ The plan also stated, “[A] very large percentage, if not all, of the supposedly Puff-branded ENDS products that these Youth are consuming are not genuine Puff products sold by EVO or its affiliate, PVG2, but rather counterfeit ENDS products imported and sold by third parties.”¹¹⁰⁸

Despite raising questions about the NYTS data, Mr. Minas said that the company discussed ways to “set Puff apart” to avoid other e-cigarettes being confused for Puff Bar, such as changing the shape of the products and making the products “more distinct.”¹¹⁰⁹ The company also discussed ramping up anti-counterfeiting efforts, but the

¹⁰⁹⁷ Minas Interview (Sept. 27, 2023).

¹⁰⁹⁸ *Id.*

¹⁰⁹⁹ Beltran Interview (Sept. 28, 2023).

¹¹⁰⁰ *Id.*

¹¹⁰¹ *Id.*

¹¹⁰² *Id.*

¹¹⁰³ Minas Interview (Sept. 27, 2023).

¹¹⁰⁴ Beltran Interview (Sept. 28, 2023).

¹¹⁰⁵ *Id.*

¹¹⁰⁶ Minas Interview (Sept. 27, 2023).

¹¹⁰⁷ “m1-10-marketing plan”.

¹¹⁰⁸ *Id.*

¹¹⁰⁹ Minas Interview (Sept. 27, 2023).

company failed to take any action.¹¹¹⁰ Despite discussing potential efforts, Mr. Beltran said that “there were no actions that we could have taken.”¹¹¹¹

After the 2022 NYTS results were released, Mr. Beltran said the company was “really shocked” and the results were “really surprising” because Puff Bar’s popularity by 2022 was “fizzling off” and other brands had taken the “top throne.”¹¹¹² Mr. Minas concluded that this data was “very skewed” and Mr. Beltran thought it was “inaccurate.”¹¹¹³ Mr. Minas said that Puff Bar refused to take any actions in response to these results because he believed that the “data wasn’t significant” or “realistic data.”¹¹¹⁴

Mr. Minas told the Subcommittee that he acquired Puff Bar, in part, because he thought he could “solve the youth use problem.”¹¹¹⁵ When asked if the 2022 NYTS results reflected progress by the company regarding youth use of its products, Mr. Minas said that he believed the company “would have made a bigger impact,” but it was difficult to implement the systems and teams needed to do so because of their lack of resources.¹¹¹⁶

According to Mr. Minas and Mr. Beltran, they engaged the Centre for Substance Use Research (“CSUR”), a Scotland-based company, to conduct a study on youth use of Puff Bar products—the one and only study the company initiated—due to their skepticism of the NYTS data.¹¹¹⁷ Mr. Minas told the Subcommittee that CSUR reached out to Puff Bar, stating that its studies and the data it was seeing did not “agree” with the NYTS data. Mr. Minas said that Puff Bar planned to use CSUR’s study for its PMTA and “basically counter” the NYTS data.¹¹¹⁸ According to CSUR, the survey used an online questionnaire and was administered to “nationally representative samples” of 1,215 youth aged 13 to 17 years and 3,370 young adults aged 18 to 24 years old in 2022.¹¹¹⁹ The CSUR study found that “[a]n estimated 0.9% [95% CI 0.4-1.6] of youth aged 13 to 17 years reported current use of the PUFF Brand which is estimated to be 190,000 [95% CI 80,000-330,000] youth aged 13 to 17 years in the United States” and “[a]n estimated 3.1% young adults aged 18 to 24 years reported past 30-day use of the

¹¹¹⁰ Beltran Interview (Sept. 28, 2023).

¹¹¹¹ *Id.*

¹¹¹² *Id.*

¹¹¹³ *Id.*; Minas Interview (Sept. 27, 2023).

¹¹¹⁴ Minas Interview (Sept. 27, 2023).

¹¹¹⁵ *Id.*

¹¹¹⁶ *Id.*

¹¹¹⁷ *Id.*; Beltran Interview (Sept. 28, 2023). CSUR is a Scotland-based company that markets itself as a “specialist research agency assisting companies with the behavioural research required to obtain a marketing authorization through the Pre-Market Tobacco Product Application (PMTA) process.” CTR. FOR SUBSTANCE USE RSCH., <https://www.csures.com/> (last visited Jan. 26, 2024).

¹¹¹⁸ Minas Interview (Sept. 27, 2023).

¹¹¹⁹ CTR. FOR SUBSTANCE USE RSCH., *Puff Study Report: An Online Survey of the Prevalence and Patterns of Use of Cigarettes and E-cigarettes Among Nationally Representative Samples of Youth, Younger Adults, and Older Adults in the United States*, at 4 (July 29, 2022). The report noted several limitations, including: “no pre-testing of participants’ comprehension of survey questions;” “reliance on accurate, honest, self-reporting of tobacco product use behaviors,” which “may be subject to response bias;” “[youth] participants may have been reluctant to report underage use of tobacco products;” and “recall bias.” *Id.* at 273-74.

PUFF Brand which is estimated to be 890,000 [95% CI 660,000-1,180,000] young adults aged 18 to 24 years in the United States.”¹¹²⁰ The study noted the “importance of continued monitoring of ENDS product use” and that its findings “provide clear evidence of the fluid nature of ENDS use amongst young adults and thus of the need for such continuous monitoring to determine the changing impact of these products within the U.S. population.”¹¹²¹

B. Puff Bar’s Co-CEOs Were Aware Youth and Young Adults Could Easily Purchase Company Products at Retail Stores

Puff Bar was aware that youth and young adults could easily purchase its products at retail stores. Mr. Beltran told the Subcommittee that he recalled one retailer located next to a college “doing great revenue numbers.”¹¹²² When the retailer admitted selling to underage users, Puff Bar decided to stop selling to the retailer.¹¹²³ Mr. Beltran said that Puff Bar “couldn’t police everything” but when it became aware of “bad apples,” he argued that the company “did the best” that it could to address the situation.¹¹²⁴ However, when asked how many retailers Puff Bar stopped selling to due to underage sales, Mr. Beltran could only recall the one retailer near the college.¹¹²⁵ In addition, the co-CEOs blamed retailers and distributors for selling e-cigarettes to underage users.¹¹²⁶ Mr. Minas believed the “laxity of store verification” led to the rise of youth vaping, but the company failed to implement efforts to address this issue.¹¹²⁷ In fact, Mr. Beltran said that the “responsibility falls on the government to enforce the regulations and laws” against retailers and distributors illegally selling e-cigarettes to underage users.¹¹²⁸

Puff Bar also received correspondence from concerned parents about underage use of the company’s e-cigarettes. The co-CEOs told the Subcommittee that, throughout 2021, the company received messages from parents stating their children

¹¹²⁰ *Id.* at 6, 11.

¹¹²¹ *Id.* at 21. The report also found: “Among youth current e-cigarette users, the most frequently reported flavors used in ENDS devices in the past 30 days include Fruit (72.2 percent), Candy (33 percent), Dessert (30.2 percent) and Mint/Menthol (26.4 percent). Among young adult current e-cigarette users aged 18 to 20 years, the most frequently reported flavors used in ENDS devices in the past 30 days include Fruit (78 percent), Menthol/Mint (50.4 percent), Candy (37.7 percent) and Other Beverages (31.4 percent). Among young adult current e-cigarette users aged 21 to 24 years, the most frequently reported flavors used in ENDS devices in the past 30 days include Fruit (73.4 percent), Menthol/Mint (49.8 percent), Candy (32.5 percent) and Dessert (24.4 percent). Among older adult current e-cigarette users, the most frequently reported flavors used in ENDS devices in the past 30 days include Fruit (55.6 percent), Menthol/Mint (33 percent), Tobacco (31.4 percent) and Candy (29.1 percent). These findings indicate that although flavor categories such as Fruit, Candy and Dessert are used by youth and young adults below the minimum age of sale, these flavor categories are primarily used by adults above the minimum age of sale.” *Id.* at 271-272.

¹¹²² Beltran Interview (Sept. 28, 2023).

¹¹²³ *Id.*

¹¹²⁴ *Id.*

¹¹²⁵ *Id.*

¹¹²⁶ *Id.*; Minas Interview (Sept. 27, 2023).

¹¹²⁷ Minas Interview (Sept. 27, 2023).

¹¹²⁸ Beltran Interview (Sept. 28, 2023).

were able to purchase Puff Bar products from retail stores.¹¹²⁹ In some cases, Puff Bar asked for more information regarding the store and location to “see what happened [and] what occurred.”¹¹³⁰ However, the company failed to act on these reports and investigate the reported retailers. Mr. Beltran explained that the company “didn’t have a good strategy” on how it was going to tackle underage sales by retailers and said, “what were you going to do?”¹¹³¹ He said that Puff Bar was not “ready to handle” any type of “policing detective work” because the company was “spread thin” and “dealing with a lot of other issues that were more specific to the operation of the business.”¹¹³² Mr. Beltran noted that he wanted to “go to every store and crack down,” but the company lacked resources and wanted to “get to a point” where it could implement these efforts, but it never did.¹¹³³

C. Puff Bar Discontinued Some Flavors That Would Appeal to Youth and Changed Flavor Names, but Its Products Continued to Resonate with Youth

When Mr. Minas and Mr. Beltran acquired Puff Bar, they decided to discontinue certain Puff Bar flavors sold by the previous owners that had youth appeal. Specifically, Mr. Minas said the company did not bring back Pink Lemonade, Cotton Candy, Pina Colada, and O.M.G. because of these flavors’ potential appeal to youth.¹¹³⁴ He explained that the company wanted to “stop naming flavors after something maybe someone underage might use, like Cotton Candy.”¹¹³⁵ He said that he also “ethically... didn’t feel comfortable” releasing a flavor named Cotton Candy because of the flavor’s appeal to youth.¹¹³⁶ Mr. Beltran told the Subcommittee that while the company maintains a “strong stance” on the notion that “everyone loves flavors regardless of age,” Puff Bar did not want to sell a flavor that was “kid sounding” or “sounds more like candy.”¹¹³⁷ For example, Puff Bar stopped selling Pink Lemonade and introduced a flavor called Lemon Ice that had the “lemonade-esque type of flavor.”¹¹³⁸ Puff Bar also wanted to avoid flavor names that sounded “too social” and decided to discontinue the flavor O.M.G., which stood for orange, mango, guava, because the company was not “trying to socially ingrain” itself.¹¹³⁹

Furthermore, Mr. Minas and Mr. Beltran said that they did not re-introduce certain Puff Bar products sold by Cool Clouds because of potential youth appeal. This included Puff Glow, a device that Mr. Beltran said “definitely” could have been viewed as “kid-

¹¹²⁹ Mr. Minas estimated that the company received “maybe less than 50” communications from parents while Mr. Beltran estimated more than 20 reports. Minas Interview (Sept. 27, 2023); Beltran Interview (Sept. 28, 2023).

¹¹³⁰ Minas Interview (Sept. 27, 2023).

¹¹³¹ Beltran Interview (Sept. 28, 2023).

¹¹³² *Id.*

¹¹³³ *Id.*

¹¹³⁴ Minas Interview (Sept. 27, 2023).

¹¹³⁵ *Id.*

¹¹³⁶ *Id.*

¹¹³⁷ Beltran Interview (Sept. 28, 2023).

¹¹³⁸ *Id.*

¹¹³⁹ *Id.*

friendly” because the device would flash bright colors when used.¹¹⁴⁰ Mr. Minas said that this product did not “align” with his and Mr. Beltran’s “vision” for the company.¹¹⁴¹

Despite claimed efforts to discontinue “kid-friendly” flavors and products, Puff Bar’s other non-traditional flavors and products continued to appeal to youth. The 2021 NYTS found that Puff Bar was the top reported brand by youth, and that eight in ten student e-cigarette users reported using flavored e-cigarettes with fruit, the most commonly used flavor category.¹¹⁴² The following year, Puff Bar again was the top reported brand and the majority of middle and high school students reported using flavored e-cigarette products.¹¹⁴³

D. Puff Bar’s Social Media Account Was Age Restricted, but the Account Reached Users Under the Age of 21

According to the co-CEOs, Puff Bar implemented an age gate on its Instagram account (@puffbar) in August 2022, when the company obtained the account from a “squatter”—a third party user who had created the account using Puff Bar’s trademarked name.¹¹⁴⁴ The age gate prohibits individuals under the age of 21 from accessing Puff Bar’s profile.¹¹⁴⁵ Although Puff Bar used an age gate on its Instagram account, according to the company’s Instagram data, Puff Bar’s profile reached users under the age of 21. Specifically, between June 15, 2023, and September 12, 2023, out of the 3,028 accounts reached by Puff Bar’s Instagram account, the top age ranges included 13-17 (7.2 percent), 18-24 (52.3 percent), 25-34 (30.7 percent), and 35-44 (6.7 percent).¹¹⁴⁶ When asked in an interview with Subcommittee staff about this data, Mr. Minas stated this was his first time seeing that the company account reached the 13-17 age range and that he had to “figure out how that is possible” and ask Instagram since Puff Bar had the age gate.¹¹⁴⁷ He also said that he believed users had to be 18 and over to have an Instagram account.¹¹⁴⁸ Similarly, Mr. Beltran stated that it was his first time seeing that Puff Bar’s account reached users age 13-17. He could not explain how or why Puff Bar’s Instagram account was reaching this age range.¹¹⁴⁹

¹¹⁴⁰ *Id.*

¹¹⁴¹ Minas Interview (Sept. 27, 2023).

¹¹⁴² 2021 *E-cigarette Use Among Middle and High School Students*, *supra* note 82.

¹¹⁴³ 2022 *E-cigarette Use Among Middle and High School Students*, *supra* note 84.

¹¹⁴⁴ Minas Interview (Sept. 27, 2023); “Screenshot 2023-06-01 at 3.23.46 PM”; Briefing with Puff Bar (June 5, 2023).

¹¹⁴⁵ “Screenshot 2023-06-01 at 3.23.46 PM”.

¹¹⁴⁶ “IMG_9776”; “IMG_9780”.

¹¹⁴⁷ Minas Interview (Sept. 27, 2023).

¹¹⁴⁸ *Id.*

¹¹⁴⁹ Beltran Interview (Sept. 28, 2023).

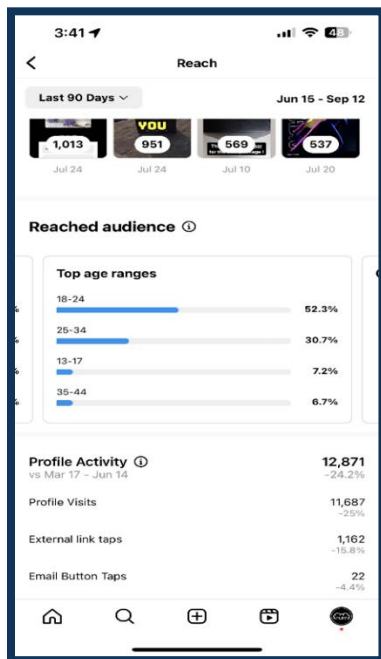


Figure 27: @puffbar Instagram Account Reached Audience Data from June 15, 2023 to September 12, 2023¹¹⁵⁰

When asked if the 18-24 age range—which comprised of over half the reached users—was Puff Bar’s target age range, Mr. Minas explained that Puff Bar did not have a target age range, but that it was “ideally” 21 and over.¹¹⁵¹ Mr. Beltran stated that he would “like to target more of the 25 to 34” age range, but noted that Instagram’s 18-24 and 25-34 age ranges were “essentially ... the overall range” the company would want to target. He added that the 21-34 age group would be the “actual range” the company would target.¹¹⁵²

E. Puff Bar Took Other Actions to Prevent Youth and Young Adults from Obtaining Its Products, but These Efforts Were Limited

Puff Bar implemented limited efforts to address underage use of its products, including age verification controls on its website and a warning insert in its packaging. Despite these efforts, Puff Bar was unsuccessful in deterring youth use of its e-cigarette products as indicated by the NYTSs. The company also reached out to anti-tobacco advocacy groups to support youth prevention efforts, but failed to connect with them.

Age Verification on PuffBar.com: In 2021, when Puff Bar relaunched, the company contracted with AgeChecker.Net (“AgeChecker”) to conduct age verification services for its website.¹¹⁵³ According to Mr. Minas, Puff Bar has used AgeChecker

¹¹⁵⁰ “IMG_9780”.

¹¹⁵¹ Minas Interview (Sept. 27, 2023).

¹¹⁵² Beltran Interview (Sept. 28, 2023).

¹¹⁵³ *Id.*; May 19, 2023 Puff Bar Response; Minas Interview (Sept. 27, 2023).

since the 2021 relaunch and continues to use the service.¹¹⁵⁴ AgeChecker verified a customer's age at checkout and used the provided name, address, and date of birth to cross-reference this information with its database.¹¹⁵⁵ A customer who failed this check was prompted to submit a government-issued photo ID, which was "manually verified" by AgeChecker's live team.¹¹⁵⁶ Statistics from the Puff Bar's age verification system indicated that the website had attempted buyers who were potentially underage. For example, from January 2021 to July 2022, the system denied over 1,500 purchases. In 121 of those instances, the buyer was underage and in 113 attempted purchases, the "ID was a fake, sample, or blocked ID."¹¹⁵⁷

Youth Prevention Outreach to Anti-Tobacco Groups: According to Mr. Minas and Mr. Beltran, in mid to late 2021, as part of its limited youth prevention efforts, Puff Bar conducted outreach to anti-tobacco organizations, such as Campaign for Tobacco-Free Kids, Truth Initiative, Flavors Hook Kids, and Parents Against Vaping E-cigarettes.¹¹⁵⁸ Mr. Minas said that that he identified these groups through media reports in which these groups spoke "poorly" about Puff Bar.¹¹⁵⁹ He said the company wanted to "change the narrative" and "change the image of the brand" and saw a "good opportunity" to work with these groups that saw the company as "the villain."¹¹⁶⁰ He said that Puff Bar wanted to offer financial support for the groups' causes and also receive "insight and ideas" regarding youth prevention efforts.¹¹⁶¹ Mr. Beltran said the company was hoping to "find a solution together" with these groups that would protect youth from e-cigarette use but also allow adult customers to enjoy Puff Bar products.¹¹⁶² According to the co-CEOs, Puff Bar did not receive a response from any of the contacted groups.¹¹⁶³

According to Mr. Beltran, Puff Bar had "light discussions, nothing too in depth" about other youth prevention efforts.¹¹⁶⁴ The company wanted to implement in-store youth prevention efforts, "but it was hard."¹¹⁶⁵ Mr. Minas said the company discussed using technology and developing a device that could turn on and off with a cell phone or would limit the amount of puffs.¹¹⁶⁶ However, he explained that this technology is "extremely expensive without funding," and Puff Bar lacked the resources to fund this

¹¹⁵⁴ Minas Interview (Sept. 27, 2023).

¹¹⁵⁵ "AgeChecker.Net How It Works".

¹¹⁵⁶ *Id.*

¹¹⁵⁷ "AGE Verification Jan 1 2021- July 2022"; "File Set 2 AgeChecker - Sheet1". The other reasons for denial include: the image uploaded was not a valid ID; the name on the ID did not match the information submitted; the name, DOB, or expiration was not visible in the image; the ID was expired; the user was banned; the image uploaded was blank or corrupted; and both sides of the ID are needed to see the required information. *Id.*

¹¹⁵⁸ June 16, 2023 Puff Bar Response; Minas Interview (Sept. 27, 2023); Beltran Interview (Sept. 28, 2023).

¹¹⁵⁹ Minas Interview (Sept. 27, 2023).

¹¹⁶⁰ *Id.*

¹¹⁶¹ *Id.*

¹¹⁶² Beltran Interview (Sept. 28, 2023).

¹¹⁶³ *Id.*; Minas Interview (Sept. 27, 2023).

¹¹⁶⁴ Beltran Interview (Sept. 28, 2023).

¹¹⁶⁵ *Id.*

¹¹⁶⁶ Minas Interview (Sept. 27, 2023).

effort.¹¹⁶⁷ Therefore, Puff Bar claimed that they reached out to these anti-tobacco advocacy groups to see if they would be interested in subsidizing some of these efforts, but never heard back.¹¹⁶⁸

Warning Insert Regarding Underage Use: For Puff Bar’s 2021 relaunch, the company developed an insert for its product packaging that warned about underage use and emphasized the 21-year age requirement to use Puff Bar products.¹¹⁶⁹ The warning stated, in part, “prevent underage usage,” “Age 21+ required to use this product,” and “[t]his device is not intended to be sold to or used by individuals under 21 years of age.”¹¹⁷⁰ Mr. Minas said that Puff Bar wanted to make “a clear statement” that the product was not for use under the age of 21, and Mr. Beltran explained that the company wanted to be “as transparent as possible” regarding some of the risks involved with using Puff Bar products.¹¹⁷¹ According to Mr. Beltran, at the time Puff Bar developed the warning insert in 2021, the company “definitely realized” that there was “some kind of youth usage issue that was starting to rise,” but did not believe it had a “specific” youth vaping problem.¹¹⁷²

V. PUFF BAR’S QUICK RISE LED TO A QUICK DOWNFALL, BUT MANAGED TO BECOME THE MOST POPULAR BRAND AMONG YOUTH ALONG THE WAY

In the Consolidated Appropriations Act, 2022, Congress explicitly authorized FDA to regulate synthetic nicotine products, addressing the so-called “Puff Bar loophole,” that the company had exploited.¹¹⁷³ Because of this action, Puff Bar was required to submit a PMTA in order to obtain FDA authorization to market its products by May 14, 2022.¹¹⁷⁴ Puff Bar submitted its PMTA on May 13, 2022.¹¹⁷⁵ On October 6, 2022, FDA issued a Refuse to File (“RTF”) determination—a determination that the application lacked sufficient information to enable a substantial review—on the company’s PMTA.¹¹⁷⁶ On the same date, FDA issued a warning letter to Puff Bar, ordering the company to cease all marketing and sales operations.¹¹⁷⁷ Rather than amending its

¹¹⁶⁷ *Id.*

¹¹⁶⁸ Beltran Interview (Sept. 28, 2023).

¹¹⁶⁹ Minas Interview (Sept. 27, 2023).

¹¹⁷⁰ “Warning Insert 2”.

¹¹⁷¹ Minas Interview (Sept. 27, 2023); Beltran Interview (Sept. 28, 2023).

¹¹⁷² Beltran Interview (Sept. 28, 2023).

¹¹⁷³ Consolidated Appropriations Act, 2022, Pub. L. No. 117-103, div. P, tit. 1, subtitle B, § 111, 136 Stat. 49, 789–90 (2022); Press Release, Ctr. for Tobacco Prods., U.S. Food & Drug Admin., New Law Clarifies FDA Authority to Regulate Synthetic Nicotine (Mar. 18, 2020), <https://www.fda.gov/tobacco-products/ctp-newsroom/new-law-clarifies-fda-authority-regulate-synthetic-nicotine>.

¹¹⁷⁴ Consolidated Appropriations Act, 2022, Pub. L. No. 117-103, div. P, tit. 1, subtitle B, § 111, 136 Stat. 49, 789–90 (2022).

¹¹⁷⁵ “10.27.2022 Response Letter to FDA Warning Letter”; “FDA-4057 12-2021 PBR”.

¹¹⁷⁶ Minas Interview (Sept. 27, 2023); Beltran Interview (Sept. 28, 2023); CTR. FOR TOBACCO PRODS., U.S. FOOD & DRUG ADMIN., *Premarket Tobacco Product Applications* (Aug. 31, 2023), <https://www.fda.gov/tobacco-products/market-and-distribute-tobacco-product/premarket-tobacco-product-applications>; “10.27.2022 Response Letter to FDA Warning Letter”.

¹¹⁷⁷ Letter from Ann Simoneau, Dir., Off. of Compliance & Enf’t, Ctr. for Tobacco Prods., U.S. Food & Drug Admin., to Nick Minas & Patrick Beltran, EVO Brands, LLC and PVG2, LLC (Oct. 6, 2022),

PMTA, Puff Bar chose to end its pursuit to obtain market authorization for its nicotine products.¹¹⁷⁸

Following the October 2022 FDA warning letter, Puff Bar ceased all marketing and sales of its nicotine products in the United States.¹¹⁷⁹ Puff Bar pivoted to offering zero-nicotine products and THC products in the United States.¹¹⁸⁰ Although Puff Bar sold its nicotine products on the U.S. market for less than three years, the company became the most popular e-cigarette brand among youth during that time. According to Mr. Minas, distributors and retailers are now reluctant to carry any Puff-branded products because “similar to ... a lot of the issues that JUUL faced,” they believe they will face scrutiny carrying products of a brand that had received a RTF determination from FDA.¹¹⁸¹ According to Mr. Minas, Puff Bar is on the “brink” of bankruptcy.¹¹⁸²

<https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/evo-brands-llc-and-pvg2-llc-dba-puff-bar-643091-10062022>.

¹¹⁷⁸ Minas Interview (Sept. 27, 2023); Beltran Interview (Sept. 28, 2023).

¹¹⁷⁹ Minas Interview (Sept. 27, 2023); Beltran Interview (Sept. 28, 2023).

¹¹⁸⁰ Minas Interview (Sept. 27, 2023); Beltran Interview (Sept. 28, 2023). Puff Bar offers two non-nicotine disposable e-cigarette products—Puff Ultra Zero and Puff Plus Zero—and are available in flavors such as Banana Ice, Cool Mint, Blue Razz Pomegranate, Raspberry Melon, Mystery, and Mango Pineapple Ice. Puff Bar, *Shop*, <https://puffbar.com/collections/puff-us> (last visited Jan. 26, 2024). The THC products are known as Puff Delta Prism, Shadow, and Gummy, and come in flavors such as Lunar Lush, Cosmic Grape, Citrus Clouds, and Blue Razz. Puff Bar, *Shop*, <https://puffdelta.com/collections/buy-thc-vapes> (last visited Jan. 26, 2024).

¹¹⁸¹ Minas Interview (Sept. 27, 2023).

¹¹⁸² *Id.*

PART VI: RECENT FDA ACTIONS CONTINUE TO FALL SHORT TO COMBAT THE YOUTH VAPING EPIDEMIC AND UNAUTHORIZED E-CIGARETTES

Puff Bar may have discontinued the sale of its synthetic nicotine-based disposable e-cigarettes in 2022, but—like JUUL before it—the company paved the way for other flavored disposable e-cigarettes to replace it as the most popular e-cigarette among youth. The 2023 NYTS found that Elf Bar—a disposable e-cigarette that comes in similar flavors offered by Puff Bar such as Blue Razz and Strawberry Kiwi¹¹⁸³—was the most popular brand reported by youth.¹¹⁸⁴ The study found that 2.1 million high school and middle school students reported current e-cigarette use, a decrease from 2.5 million students in 2022.¹¹⁸⁵ Despite the decrease of 400,000, e-cigarettes were the most commonly used tobacco product among students for the tenth year in a row. Similar to past NYTS results, nearly nine out of ten students used flavored e-cigarettes, with fruit, candy, mint, and menthol being the most common flavors used.¹¹⁸⁶

FDA has struggled to combat the proliferation of e-cigarettes, especially flavored disposable e-cigarettes that continue to appeal to youth. FDA has failed to review e-cigarette product applications in a timely manner and has blown past a court-ordered deadline by nearly two years. In 2022, FDA was given the authority to regulate synthetic nicotine products and required applications for those products to be filed with the agency by May 2022; however, FDA continues to review those applications. FDA has a variety of enforcement mechanisms to address unauthorized e-cigarettes that appeal to youth, including warning letters, permanent injunctions, and civil money penalties, but the agency has only recently increased use of these mechanisms. A December 2022 evaluation by the Reagan-Udall Foundation identified many shortcomings regarding FDA's efforts to regulate e-cigarettes, including FDA's "reactive mode" to prevent youth use of tobacco products.¹¹⁸⁷

¹¹⁸³ *Best Elf Bar Flavors 2023*, VAPING360, <https://vaping360.com/best-beginner-e-cigs-vapes/best-elf-bar-flavors/>.

¹¹⁸⁴ Press Release, U.S. Food & Drug Admin., National Survey Shows Drop in E-Cigarette Use Among High School Students (Nov. 2, 2023), <https://www.fda.gov/news-events/press-announcements/national-survey-shows-drop-e-cigarette-use-among-high-school-students> [hereinafter U.S. Food & Drug Admin., National Survey].

¹¹⁸⁵ *Id.*; *2023 Tobacco Product Use Among U.S. Middle and High School Students*, *supra* note 85, at 1175.

¹¹⁸⁶ U.S. Food & Drug Admin., National Survey, *supra* note 1184; *2023 Tobacco Product Use Among U.S. Middle and High School Students*, *supra* note 85, at 1175.

¹¹⁸⁷ REAGAN-UDALL FOUND. FOR FDA, OPERATIONAL EVALUATION OF CERTAIN COMPONENTS OF FDA'S TOBACCO PROGRAM, at 5 (Dec. 19, 2022), <https://reaganudall.org/sites/default/files/2022-12/Tobacco%20report%20210pm.pdf> [hereinafter REAGAN-UDALL FOUND. REPORT].

I. THE 2023 NYTS RESULTS AND FDA’S STRUGGLE TO COMBAT UNAUTHORIZED E-CIGARETTES

On November 2, 2023, FDA and CDC released data from the 2023 NYTS.¹¹⁸⁸ The data showed that more than 2.1 million youth—1.56 million high school students and 550,000 middle school students—currently used e-cigarettes.¹¹⁸⁹ Encouragingly, the survey indicated a decline in e-cigarette use among high school students—from 14.1 percent in 2022 to 10 percent in 2023.¹¹⁹⁰ However, there was no significant change during 2022-2023 for current use of e-cigarettes by middle school students, and current overall tobacco use increased from 4.5 percent to 6.6 percent.¹¹⁹¹

For the tenth year in a row, e-cigarettes were the most commonly used tobacco product among youth, and disposable e-cigarette products were the most commonly used product type.¹¹⁹² However, the most popular brands of e-cigarettes included both disposable and cartridge-based brands. The most popular brands reported by youth were Elf Bar (56.7 percent), Esco Bars (21.6 percent), Vuse (20.7 percent), JUUL (16.5 percent), and Mr. Fog (13.6 percent).¹¹⁹³ Among middle and high school students who reported current e-cigarette use, nearly nine out of ten students used flavored e-cigarettes (89.4 percent), with fruit, candy, mint, and menthol being the most common flavors used, similar to past NYTS results.¹¹⁹⁴ Additionally, the 2023 NYTS asked about the use of flavors that included the word “ice” or “iced” in the name for the first time. Over half (57.9 percent) of students reporting current e-cigarette use reported using flavors with those words in the name of the product, suggesting that the use of flavored products among youth might be higher than previously reported.¹¹⁹⁵

Elf Bar has not been authorized by FDA and has become the most popular e-cigarette among youth in 2023. In fact, out of the top five popular brands reported in the 2023 NYTS, only certain Vuse e-cigarettes have been authorized by FDA.¹¹⁹⁶ This is indicative of a greater problem—the vast market of unauthorized e-cigarettes in the United States. According to industry sales data, the number of unique e-cigarette

¹¹⁸⁸ U.S. Food & Drug Admin., National Survey, *supra* note 1184; *2023 Tobacco Product Use Among U.S. Middle and High School Students*, *supra* note 85.

¹¹⁸⁹ *2023 Tobacco Product Use Among U.S. Middle and High School Students*, *supra* note 85, at 1179.

¹¹⁹⁰ U.S. Food & Drug Admin., National Survey, *supra* note 1184; *2023 Tobacco Product Use Among U.S. Middle and High School Students*, *supra* note 85, at 1178.

¹¹⁹¹ U.S. Food & Drug Admin., National Survey, *supra* note 1184; *2023 Tobacco Product Use Among U.S. Middle and High School Students*, *supra* note 85, at 1175-78.

¹¹⁹² U.S. Food & Drug Admin., National Survey, *supra* note 1184; *2023 Tobacco Product Use Among U.S. Middle and High School Students*, *supra* note 85, at 1175.

¹¹⁹³ U.S. Food & Drug Admin., National Survey, *supra* note 1184; *2023 Tobacco Product Use Among U.S. Middle and High School Students*, *supra* note 85, at 1175.

¹¹⁹⁴ U.S. Food & Drug Admin., National Survey, *supra* note 1184; *2023 Tobacco Product Use Among U.S. Middle and High School Students*, *supra* note 85, at 1175.

¹¹⁹⁵ U.S. Food & Drug Admin., National Survey, *supra* note 1184; *2023 Tobacco Product Use Among U.S. Middle and High School Students*, *supra* note 85, at 1175.

¹¹⁹⁶ U.S. FOOD & DRUG ADMIN., *E-Cigarettes Authorized by the FDA* (Aug. 2023), <https://digitalmedia.hhs.gov/tobacco/hosted/E-Cigarettes-Authorized-FDA-Aug23.pdf>.

products for sale in the United States stood at 11,500 as of December 2023, up from 9,000 in June 2023, and has more than tripled since 2020; the vast majority are unauthorized disposable e-cigarettes from China.¹¹⁹⁷ A June 2023 CDC study found that the number of e-cigarette brands increased by 46 percent from 2020 to 2022 to nearly 260 brands, each of which may market thousands of different products.¹¹⁹⁸ According to data from IRI, an analytics firm that collects barcode scanner sales from convenience stores, gas stations, and other retailers, cheap disposable e-cigarettes made up 40 percent of the approximately \$7 billion retail market for e-cigarettes in 2022.¹¹⁹⁹ In addition, IRI data showed that over 5,800 unique disposable e-cigarette products are now being sold in a variety of flavors, up 1,500 percent from 365 products in early 2020, when FDA banned all flavors except menthol and tobacco from cartridge-based e-cigarettes like JUUL.¹²⁰⁰

These staggering statistics demonstrate FDA's lack of control over the e-cigarette market. Despite reviewing premarket applications and enforcement efforts, thousands of unauthorized e-cigarettes continue to flood the marketing. FDA issued import alerts to block imports of unauthorized e-cigarettes.¹²⁰¹ However, e-cigarette brands can easily work around the import block by renaming their products and changing the shipping address.¹²⁰² Elf Bar did exactly that, and iMiracle Shenzhen Technology ("iMiracle Shenzhen")—Elf Bar's parent company—rebranded it to EBCreate approximately two weeks after FDA announced an import ban in May.¹²⁰³ CTP Director Dr. King stated that the agency is monitoring situations where companies change their branding to avoid detection.¹²⁰⁴ FDA has not issued a warning letter to EBCreate or its parent company iMiracle Shenzhen.¹²⁰⁵

FDA has been dealt a difficult challenge in terms of the volume, scale, and quickly changing landscape of the e-cigarette market, but the agency has failed to review e-cigarette applications promptly and has not fully utilized its enforcement tools,

¹¹⁹⁷ Matthew Perrone, *US seizes more illegal e-cigarettes, but thousands of new ones are launching*, ASSOCIATED PRESS (Dec. 30, 2023), <https://apnews.com/article/ecigarettes-elf-bar-fda-teen-vaping-imports-be95ce8a7942619c5b60f40a37bb9cf5>.

¹¹⁹⁸ Fatmah Romeh M. Ali et al., *E-cigarette Unit Sales by Product and Flavor Type, and Top-Selling Brands, United States, 2020–2022*, 72 MORBIDITY & MORTALITY WKLY. REP. 672-677 (June 23, 2023).

¹¹⁹⁹ Matthew Perrone, *Thousands of unauthorized vapes are pouring into the US despite the FDA crackdown on fruity flavors*, ASSOCIATED PRESS (June 26, 2023), <https://apnews.com/article/fda-vapes-vaping-elf-bar-juul-80b2680a874d89b8d651c5e909e39e8f>.

¹²⁰⁰ *Id.*

¹²⁰¹ See e.g., U.S. FOOD & DRUG ADMIN., Import Alert 98-06 (Oct. 31, 2023), https://www.accessdata.fda.gov/cms_ia/importalert_1163.html.

¹²⁰² Matthew Perrone, *Elf Bar finds an easy way around US vape import ban: a name change*, ASSOCIATED PRESS (Oct. 13, 2023), <https://apnews.com/article/ecigarettes-elf-bar-fda-disposable-vaping-5245aed253ca9cdcf119483bd9cee1f1>.

¹²⁰³ *Id.*

¹²⁰⁴ *Id.*

¹²⁰⁵ *Id.*

including fines and permanent injunctions, to remove products from the market and combat youth access to unauthorized e-cigarettes.¹²⁰⁶

II. FDA HAS FAILED TO REVIEW E-CIGARETTE PMTAS PROMPTLY

On April 22, 2020, in light of the challenges presented by the COVID-19 pandemic, the U.S. District Court for the District of Maryland granted a motion for a 120-day extension of the premarket authorization application deadline, pushing the deadline from May 12, 2020 to September 9, 2020.¹²⁰⁷ The extension allowed companies that submitted an application by the September 9 deadline to market their tobacco products for up to one year from the deadline.¹²⁰⁸ The court also ordered FDA to review all PMTAs by September 9, 2021.¹²⁰⁹ The agency did not meet this deadline and initially stated that it would complete review of applications by June 2023.¹²¹⁰ The FDA pushed that deadline to December 2023—more than two years since the court-ordered deadline—but failed to meet it, citing delayed amendments to the applications and adjustments to the review process following legal challenges.¹²¹¹ The agency now expects to review all PMTAs by June 30, 2024.¹²¹²

FDA received PMTAs for nearly 26 million e-cigarette products, including applications for 6.7 million products submitted by the September 2020 deadline, applications for more than 18 million products submitted after the September 2020 deadline, and nearly one million applications for NTN products submitted by May 14,

¹²⁰⁶ Yuki Noguch, *They're illegal. So why is it so easy to buy the disposable vapes favored by teens?*, NPR (July 14, 2023), <https://www.npr.org/sections/health-shots/2023/07/14/1186291971/theyre-illegal-so-why-is-it-so-easy-to-buy-the-disposable-vapes-favored-by-teens>.

¹²⁰⁷ Press Release, U.S. Food & Drug Admin., Coronavirus (COVID-19) Update: Court Grants FDA's Request for Extension of Premarket Review Submission Deadline for Certain Tobacco Products Because of Impacts from COVID-19 (Apr. 23, 2020), <https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-court-grants-fdas-request-extension-premarket-review-submission-deadline>; Order at 1, *Am. Acad. of Pediatrics v. Food & Drug Admin.*, 379 F. Supp. 3d 461 (D. Md. 2019) (Case No. 8:18-cv-883 PWG) (No. 182).

¹²⁰⁸ U.S. Food & Drug Admin., Coronavirus (COVID-19) Update, *supra* note 1207.

¹²⁰⁹ Order at 1, *Am. Acad. of Pediatrics v. Food & Drug Admin.*, 379 F. Supp. 3d 461 (D. Md. 2019) (Case No. 8:18-cv-883 PWG) (No. 182); Press Release, Campaign for Tobacco-Free Kids, One Year After Deadline for FDA Action, Flavored E-Cigarettes Remain Widely Available and America's Kids Remain at Risk (Sept. 9, 2022), https://www.tobaccofreekids.org/press-releases/2022_09_09_fda-deadline.

¹²¹⁰ Status Report at 3, *Am. Acad. of Pediatrics v. Food & Drug Admin.*, 379 F. Supp. 3d 461 (D. Md. 2019) (Case No. 8:18-cv-883 PWG) (No. 205); Campaign for Tobacco-Free Kids, One Year After Deadline for FDA Action, *supra* note 1209.

¹²¹¹ Status Report at 2, *Am. Acad. of Pediatrics v. Food & Drug Admin.*, 379 F. Supp. 3d 461 (D. Md. 2019) (Case No. 8:18-cv-883 PWG) (No. 211); Status Report at 2-3, *Am. Acad. of Pediatrics v. Food & Drug Admin.*, 379 F. Supp. 3d 461 (D. Md. 2019) (Case No. 8:18-cv-883 PWG) (No. 218). See also Liz Szabo, *E-Cigs Are Still Flooding the US, Addicting Teens with Higher Nicotine Doses*, KFF HEALTH NEWS (June 26, 2023), <https://kffhealthnews.org/news/article/e-cigs-are-still-flooding-the-us-addicting-teens-with-higher-nicotine-doses/>.

¹²¹² Status Report at 2-3, *Am. Acad. of Pediatrics v. Food & Drug Admin.*, 379 F. Supp. 3d 461 (D. Md. 2019) U.S. FOOD & DRUG ADMIN. (No. 218).

2022.¹²¹³ According to FDA, it has made determinations on over 99 percent of those products, rejecting millions of e-cigarettes and authorizing 23 e-cigarette products in only tobacco flavor.¹²¹⁴

FDA has authorized only tobacco-flavored e-cigarettes manufactured by Logic Technology Development LLC, NJOY LLC, and R.J. Reynolds Vapor Company.¹²¹⁵ FDA has not authorized any flavored e-cigarette, including menthol. FDA has issued approximately 280 marketing denial orders for flavored e-cigarettes, including products from some of the largest e-cigarette companies.¹²¹⁶ For example, in January 2023, FDA issued MDOs against other Vuse e-cigarette products, including the Vuse Vibe Tank, the Vuse Ciro Cartridge, and the Vuse Solo Replacement Cartridge, all in Menthol flavor.¹²¹⁷ However, the U.S. Court of Appeals for the Fifth Circuit granted an administrative stay at the request of R.J. Reynolds, allowing the company to continue selling menthol-flavored e-cigarettes pending further order of the court.¹²¹⁸ The 2022 NYTS found that Vuse was the second most popular e-cigarette brand among youth and the third most popular brand in the 2023 NYTS.¹²¹⁹

Furthermore, JUUL received a MDO on June 23, 2022 and was ordered to remove its products from the market.¹²²⁰ A few weeks later, however, FDA administratively stayed JUUL's denial order because it had determined that there "are

¹²¹³ Press Release, U.S. Food & Drug Admin., FDA Makes Determinations On More Than 99% of the 26 Million Tobacco Products For Which Applications Were Submitted (Mar. 15, 2023), <https://www.fda.gov/tobacco-products/ctp-newsroom/fda-makes-determinations-more-99-26-million-tobacco-products-which-applications-were-submitted>.

¹²¹⁴ *Id.*; U.S. FOOD & DRUG ADMIN., *Premarket Tobacco Product Marketing Granted Orders* (Nov. 22, 2023), <https://www.fda.gov/tobacco-products/premarket-tobacco-product-applications/premarket-tobacco-product-marketing-granted-orders>.

¹²¹⁵ U.S. FOOD & DRUG ADMIN., *E-Cigarettes Authorized by the FDA* (Aug. 2023), <https://digitalmedia.hhs.gov/tobacco/hosted/E-Cigarettes-Authorized-FDA-Aug23.pdf>.

¹²¹⁶ Press Release, U.S. Food & Drug Admin., FDA Denies Marketing of Six Flavored Vuse Alto E-Cigarette Products Following Determination They Do Not Meet Public Health Standard (Oct. 12, 2023), <https://www.fda.gov/news-events/press-announcements/fda-denies-marketing-six-flavored-vuse-alto-e-cigarette-products-following-determination-they-do-not-meet>; U.S. FOOD & DRUG ADMIN., *List of Tobacco Products Marketing Orders* (Jan. 22, 2024), <https://www.fda.gov/tobacco-products/market-and-distribute-tobacco-product/tobacco-products-marketing-orders#Premarket%20Tobacco%20Product%20Applications%20> (follow "PMTA" hyperlink; then select CSV file available at "companies that have been issued a marketing denial order").

¹²¹⁷ Press Release, U.S. Food & Drug Admin., FDA Denies Marketing of Two Vuse Menthol E-Cigarette Products Following Determination They Do Not Meet Public Health Standard (Jan. 24, 2023), <https://www.fda.gov/news-events/press-announcements/fda-denies-marketing-two-vuse-menthol-e-cigarette-products-following-determination-they-do-not-meet>; Press Release, U.S. Food & Drug Admin., FDA Denies Marketing of Two Vuse Solo Menthol E-Cigarette Products (Mar. 17, 2023), <https://www.fda.gov/news-events/press-announcements/fda-denies-marketing-two-vuse-solo-menthol-e-cigarette-products>.

¹²¹⁸ R.J. Reynolds Vapor Co., et al. v. U.S. Food and Drug Administration, et al., No. 23-60037 (5th Cir. 2023) (order granting temporary stay).

¹²¹⁹ 2022 *E-cigarette Use Among Middle and High School Students*, *supra* note 84; 2023 *Tobacco Product Use Among U.S. Middle and High School Students*, *supra* note 85.

¹²²⁰ Press Release, U.S. Food & Drug Admin., FDA Denies Authorization to Market JUUL Products (June 23, 2022), <https://www.fda.gov/news-events/press-announcements/fda-denies-authorization-market-juul-products>.

scientific issues unique to the JUUL application that warrant additional review.”¹²²¹ FDA noted that it did “not intend to take enforcement action against the products subject to this marketing denial order while the administrative stay is in place.”¹²²² A decision on JUUL’s application is still pending, but FDA has said it would finalize its decision by the end of 2023.¹²²³

III. FDA OBTAINED AUTHORITY OVER NON-TOBACCO NICOTINE PRODUCTS LIKE SYNTHETIC NICOTINE AND HAS YET TO REVIEW ALL RELATED PMTAS

As discussed above, the 2016 Deeming Rule extended FDA’s tobacco product authorities to include e-cigarettes. However, a loophole remained in the law and allowed companies using non-tobacco nicotine (“NTN”), or synthetic nicotine, to evade FDA oversight.¹²²⁴ In response to the increased use of synthetic nicotine by popular e-cigarette companies, including Puff Bar, the Consolidated Appropriations Act, 2022, which became effective on April 14, 2022, clarified that FDA’s authority included regulating tobacco products containing nicotine “from any source,” including synthetic nicotine.¹²²⁵ Manufacturers of NTN products were required to submit a PMTA to FDA by May 14, 2022.¹²²⁶ FDA received applications for nearly one million NTN products by that date.¹²²⁷ As of October 2023, FDA has accepted over 9,500 applications, issued refuse-to-accept (RTA) letters for more than 926,000 products, and has made determinations on over 98 percent of the applications.¹²²⁸ To date, no NTN product has received marketing approval from FDA.¹²²⁹

IV. FDA ENFORCEMENT ACTIONS RELATED TO E-CIGARETTES

FDA has a variety of enforcement mechanisms to address unauthorized e-cigarettes that appeal to youth, including warning letters, permanent injunctions, and civil money penalties (“CMPs”). Until recently, FDA has been reluctant to use these

¹²²¹ *Id.*

¹²²² *Id.*

¹²²³ Christina Jewett, *Illicit E-Cigarettes Flood Stores as F.D.A. Struggles to Combat Imports*, N.Y. TIMES (Oct. 10, 2023), <https://www.nytimes.com/2023/10/10/health/illegal-vapes-ecigarettes-fda.html>.

¹²²⁴ Christina Jewett, *The Loophole That’s Fueling a Return to Teenage Vaping*, N.Y. TIMES (Mar. 8, 2022), <https://www.nytimes.com/2022/03/08/health/vaping-fda-nicotine.html>; *How companies like Puff Bar have avoided FDA regulation: “The industry can innovate around it”*, CBS NEWS (Dec. 15, 2021), <https://www.cbsnews.com/news/puff-bar-fda-regulation-loopholes/>.

¹²²⁵ Pub. L. 117–103 (2022); Press Release, U.S. Food & Drug Admin., *New Law Clarifies FDA Authority to Regulate Synthetic Nicotine* (Mar. 18, 2022), <https://www.fda.gov/tobacco-products/ctp-newsroom/new-law-clarifies-fda-authority-regulate-synthetic-nicotine>; Federal Food Drug & Cosmetics Act § 201(rr)(1), 21 U.S.C. § 321(rr)(1) (2023).

¹²²⁶ Press Release, U.S. Food & Drug Admin., *Requirements for Products Made with Non-Tobacco Nicotine Take Effect April 14* (Apr. 13, 2022), <https://www.fda.gov/tobacco-products/ctp-newsroom/requirements-products-made-non-tobacco-nicotine-take-effect-april-14>.

¹²²⁷ U.S. FOOD & DRUG ADMIN., *Regulation and Enforcement of Non-Tobacco Nicotine (NTN) Products* (Nov. 6, 2023), <https://www.fda.gov/tobacco-products/products-ingredients-components/regulation-and-enforcement-non-tobacco-nicotine-ntn-products>.

¹²²⁸ *Id.*

¹²²⁹ *Id.*

legal authorities and has mainly issued warning letters.¹²³⁰ Generally, when FDA finds that a retailer or manufacturer has violated FDA regulations, FDA will send a warning letter.¹²³¹ The letter will identify the violation and provide guidance on how to correct the issue as well as a timeframe for the company to inform FDA of its plans for correcting the violation.¹²³² Failure to correct violations identified in a warning letter can result in further action by FDA such as CMPs, seizure, and/or injunction.¹²³³ As discussed above, Puff Bar received warning letters from FDA. Recently, FDA issued warning letters to seven online retailers for selling and/or distributing unauthorized e-cigarettes that used “youth-appealing toys and drink containers, including milk cartons, soft drink bottles, and slushies.”¹²³⁴ As of November 2023, FDA has issued approximately 630 warning letters to e-cigarette manufacturers and distributors and issued more than 400 warning letters to retailers for the sale of unauthorized e-cigarettes.¹²³⁵

On October 18, 2022, DOJ, on behalf of FDA, issued FDA’s first permanent injunctions against six manufacturers of unauthorized e-cigarettes.¹²³⁶ These manufacturers had failed to submit a PMTA for their e-cigarettes and continued to illegally manufacture and sell their products, despite receiving warnings from the agency.¹²³⁷ Dr. Brian King, Director of FDA’s CTP, stated, “Today’s enforcement actions represent a significant step for the FDA in preventing tobacco product manufacturers from violating the law.”¹²³⁸

On February 22, 2023, FDA filed its first CMP complaints against four e-liquid manufacturers for manufacturing and selling unauthorized e-liquids.¹²³⁹ These complaints were the first CMPs filed against tobacco product manufacturers for violating the premarket review requirements for new tobacco products.¹²⁴⁰ For each complaint,

¹²³⁰ See Nichoals Florko & Elissa Welle, *The FDA stands by as the vaping industry flouts its orders*, STAT (Aug. 24, 2022), <https://www.statnews.com/2022/08/24/the-fda-stands-by-as-the-vaping-industry-flouts-its-orders/>.

¹²³¹ U.S. FOOD & DRUG ADMIN., *About Warning and Close-Out Letters* (Apr. 29, 2019), <https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/about-warning-and-close-out-letters>.

¹²³² *Id.*

¹²³³ Press Release, U.S. Food & Drug Admin., FDA Continues to Implement Law Regarding Non-Tobacco Nicotine Products (July 5, 2023), <https://www.fda.gov/tobacco-products/ctp-newsroom/fda-continues-implement-law-regarding-non-tobacco-nicotine-products>.

¹²³⁴ Press Release, U.S. Food & Drug Admin., FDA Warns Retailers to Stop Selling Illegal Youth-Appealing E-Cigarettes Disguised as Everyday Items (Nov. 16, 2023), <https://www.fda.gov/tobacco-products/ctp-newsroom/fda-warns-retailers-stop-selling-illegal-youth-appealing-e-cigarettes-disguised-everyday-items>.

¹²³⁵ *Id.*

¹²³⁶ Press Release, U.S. Food & Drug Admin., FDA, DOJ Seek Permanent Injunctions Against Six E-cigarette Manufacturers (Oct. 18, 2022), <https://www.fda.gov/news-events/press-announcements/fda-doj-seek-permanent-injunctions-against-six-e-cigarette-manufacturers>.

¹²³⁷ *Id.*

¹²³⁸ *Id.*

¹²³⁹ Press Release, U.S. Food & Drug Admin., FDA Files Civil Money Penalty Complaints Against Four E-Cigarette Product Manufacturers (Feb. 22, 2023), <https://www.fda.gov/news-events/press-announcements/fda-files-civil-money-penalty-complaints-against-four-e-cigarette-product-manufacturers>.

¹²⁴⁰ *Id.*

FDA sought the statutory maximum of \$19,192 for a single violation against each manufacturer.¹²⁴¹ As of January 2024, FDA has filed CMPs against 48 different e-cigarette manufacturers.¹²⁴² FDA has also used CMPs to target e-cigarette retailers. On September 28, 2023, FDA filed CMP complaints against 22 retailers for illegally selling Elf Bar e-cigarettes, a popular brand among youth.¹²⁴³ Although FDA has previously issued CMP complaints to retailers for selling unauthorized tobacco products, this was the first time the agency requested the maximum penalty of \$19,192 for a single violation from each retailer.¹²⁴⁴ That same day, FDA issued 168 warning letters to brick-and-mortar retailers for selling unauthorized Elf Bar e-cigarettes.¹²⁴⁵ As of December 5, 2023, FDA has filed CMPs against 67 retailers for the sale of unauthorized tobacco products.¹²⁴⁶

FDA has increased its use of “import refusals” of tobacco products to stem the proliferation of e-cigarettes from abroad. Import refusals occur when FDA determines that the products in a foreign shipment of goods violate FDA laws and regulations, including the FD&C. Once refused, FDA, working with the U.S. Customs and Border Protection, detains the products and orders them to be exported or destroyed.¹²⁴⁷ From 2016 through 2019, the agency conducted fewer than 10 refusals of tobacco product shipments per fiscal year.¹²⁴⁸ Between 2020 and 2023 refusal rates jumped, averaging roughly 120 per fiscal year, and in the first few months of fiscal year 2024 the agency has already handled over 300 refusals, almost all of which were e-cigarette products from China that lacked valid FDA marketing authorization.¹²⁴⁹ Despite these product seizures, the number of e-cigarette products available for sale continues to increase, and authorized products lag far behind their unauthorized competitors, representing just 2.4 percent of the U.S. vaping market in 2023.¹²⁵⁰

¹²⁴¹ *Id.*

¹²⁴² U.S. FOOD & DRUG ADMIN., *Advisory and Enforcement Actions Against Industry for Unauthorized Tobacco Products* (Jan. 19, 2024), <https://www.fda.gov/tobacco-products/compliance-enforcement-training/advisory-and-enforcement-actions-against-industry-unauthorized-tobacco-products#4>.

¹²⁴³ Press Release, U.S. Food & Drug Admin., *FDA Seeks Fines Against 22 Retailers for Selling Illegal Youth-Appealing E-Cigarettes* (Sept. 28, 2023), <https://www.fda.gov/news-events/press-announcements/fda-seeks-fines-against-22-retailers-selling-illegal-youth-appealing-e-cigarettes>.

¹²⁴⁴ *Id.*

¹²⁴⁵ *Id.*; U.S. FOOD & DRUG ADMIN., *Elf Bar/EB Design Warning Letters - Sept. 28, 2023 Announcement*, <https://www.fda.gov/media/172546/download?attachment>.

¹²⁴⁶ U.S. FOOD & DRUG ADMIN., *Retailer Civil Money Penalty Complaints - Dec. 5, 2023 Announcement*, <https://www.fda.gov/media/172548/download?attachment>.

¹²⁴⁷ U.S. FOOD & DRUG ADMIN., *Import Refusals* (Nov. 17, 2022), <https://www.fda.gov/industry/fda-import-process/import-refusals>.

¹²⁴⁸ U.S. FOOD & DRUG ADMIN., *Import Refusals Compliance Dashboards* <https://datadashboard.fda.gov/ora/cd/imprefusals.htm> (last visited Jan. 26, 2024).

¹²⁴⁹ *Id.*

¹²⁵⁰ Perrone, *US seizes more illegal e-cigarettes*, *supra* note 1197.

V. THE REAGAN-UDALL FOUNDATION EVALUATION FOUND TROUBLING ISSUES WITH FDA CTP

In September 2022, the Reagan-Udall Foundation (“RUF”) began an independent evaluation of FDA CTP, at the request of FDA Commissioner Dr. Robert Califf.¹²⁵¹ The evaluation focused on four program areas for CTP: regulations and guidance, application review, compliance and enforcement, and communication with the public and other stakeholders.¹²⁵² On December 19, 2022, RUF released its findings and made the following key points:¹²⁵³

- CTP has been mainly in a “reactive mode” and “should transition to becoming a more proactive and strategic program.”
- “CTP has a critical mission to protect the public health from tobacco-related disease and death,” but it is “a government regulatory program with a duty to run efficiently, fairly, and transparently.” This duty should be “carried out to the best of the Center’s ability.”
- CTP should implement “process improvements and identify and address the policy and scientific questions that underpin its regulatory framework.”
- CTP should “work with other entities on strategies to clear the market of illegal tobacco products more rapidly” and that “enforcement of the premarket requirements in the tobacco laws, particularly to help prevent youth use of tobacco products, requires the involvement and support of agencies other than FDA.”¹²⁵⁴

RUF also found that FDA’s “failure to take timely enforcement action jeopardizes public health and undermines FDA’s credibility and effectiveness in tobacco product regulation” and noted that FDA had “not been transparent regarding the reasons it has failed to clear the market of illegal products, or even whether its policy preference is to do so.”¹²⁵⁵ The report noted that FDA’s “current process of bringing enforcement actions is cumbersome, and ultimate decisions on whether to take enforcement action rest with DOJ rather than FDA,” and that “FDA’s tobacco cases must compete for DOJ resources with other issues that require DOJ attention.”¹²⁵⁶ RUF made 15 recommendations, including improving agency transparency, developing a clear and predictable framework for PMTA submission and reviews, and establishing an interagency task force to make enforcement a priority.¹²⁵⁷

¹²⁵¹ *Operational Evaluation of FDA’s Tobacco Program*, REAGAN-UDALL FOUND. FOR FDA, <https://reaganudall.org/operational-evaluation-fdas-tobacco-program>.

¹²⁵² *Id.*

¹²⁵³ REAGAN-UDALL FOUND. REPORT, *supra* note 1187, at 4.

¹²⁵⁴ *Id.*

¹²⁵⁵ *Id.* at 23.

¹²⁵⁶ *Id.* at 22-23.

¹²⁵⁷ *Id.* at 14-23.

On February 24, 2023, CTP Director Dr. King issued CTP's response to the RUF report and outlined the Center's plan to respond to the evaluation.¹²⁵⁸ For example, CTP initiated the development of a comprehensive five-year strategic plan, the development of a "more efficient" framework for PMTA reviews, and convened a summit related to enforcement with senior officials from HHS, FDA, and DOJ.¹²⁵⁹ As part of its plan to be more transparent, the agency developed a webpage updating the public on its actions to address the RUF recommendations.¹²⁶⁰

¹²⁵⁸ Press Release, U.S. Food & Drug Admin., An All-Center Approach: CTP's Response to the Reagan-Udall Foundation Evaluation Report (Feb. 24, 2023), <https://www.fda.gov/tobacco-products/ctp-newsroom/all-center-approach-ctps-response-reagan-udall-foundation-evaluation-report>.

¹²⁵⁹ *Id.*

¹²⁶⁰ U.S. FOOD & DRUG ADMIN., *Actions to Address Recommendations from the Reagan-Udall Evaluation of CTP* (updated Dec. 18, 2023), <https://www.fda.gov/tobacco-products/about-center-tobacco-products-ctp/actions-address-recommendations-reagan-udall-evaluation-ctp>.

CONCLUSION

Although recent FDA enforcement priorities have targeted certain flavored e-cigarettes, these actions have not fully addressed the range of products driving youth usage. In the absence of a comprehensive federal approach, local and state governments have taken a more active role in restricting youth access to flavored e-cigarette products. According to the Campaign for Tobacco-Free Kids, as of November 30, 2023, at least 375 localities in 12 different states and the District of Columbia have passed some form of restriction on the sale of flavored tobacco products.¹²⁶¹ Massachusetts was the first state to ban flavored e-cigarettes in November 2019. In 2020, at least four other states—New Jersey, New York, Rhode Island, and California—enacted bans on the sale of flavored e-cigarettes. Short of full bans on flavored products, other states have passed laws restricting the sale of products to youth and young adults. For example, all 50 states, the District of Columbia, and U.S. territories have passed legislation prohibiting the sale of e-cigarettes to persons under the age of 21.¹²⁶²

Medical research, government studies, and public surveys have thoroughly documented the risk e-cigarettes pose to youth and the role that flavored products play in attracting these users. As shown above, JUUL captured over 70 percent of the e-cigarette market, in part, because of its flavors and youthful marketing. Puff Bar became the most popular e-cigarette brand among youth with its portfolio of non-traditional flavors. As Congress and the Executive Branch consider how best to protect current and future generations of Americans from the dangers of nicotine addiction, the example of JUUL, Puff Bar, and federal efforts to regulate the e-cigarette industry will be instructive. Although certain adult users may have a legitimate need for flavored products, policymakers must balance this need with preventing youth and young adult usage. The Subcommittee's investigation makes clear that the federal government has yet to strike the appropriate balance and further action is needed.

¹²⁶¹ CAMPAIGN FOR TOBACCO-FREE KIDS, *States & Localities That Have Restricted the Sale of Flavored Tobacco Products* (Dec. 29, 2023), <https://assets.tobaccofreekids.org/factsheets/0398.pdf>.

¹²⁶² U.S. CTRS. FOR DISEASE CONTROL & PREVENTION, *STATE System E-Cigarette Fact Sheet*, <https://www.cdc.gov/statesystem/factsheets/ecigarette/ECigarette.html> (last visited Jan. 26, 2024).