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Better Late than Never: Electronic Cigarettes and a Failed Federal Regulatory Response

Cameron McCue

BETTER LATE THAN NEVER: ELECTRONIC CIGARETTES AND A FAILED FEDERAL REGULATORY RESPONSE

CAMERON MCCUE†

Over the past fifty-plus years, government officials, regulators, lawyers, lobbyists, and the like have struggled to grapple with the public health risks posed by the tobacco industry. Efforts to curb tobacco use among adults and youth have proven relatively successful in recent years. But the meteoric rise of electronic cigarettes over the last two decades has thrust policymakers back into the fray with the tobacco industry, inevitably leading one to ask the question: are we right back where we started? Electronic cigarettes—also known as "e-cigs" or "vapes"—contain a small battery that heats a nicotine-infused liquid to produce a warm, odorless vapor that can be inhaled by the user. In the past two decades, there have been several unsatisfactory attempts by federal regulators to comprehensively address the rise of this industry, and today, millions of U.S. youth report regularly using electronic cigarettes. While much of the damage may have already been done, the federal government must learn from its failures and act quickly to comprehensively address this now multi-billion-dollar industry. Regulators should enact policies that discourage youth from ever using nicotine in the first place while remaining careful not to totally preclude adult smokers from making the switch to a potentially safer alternative to combustible cigarettes.

I. INTRODUCTION

On the morning of April 14, 1994, chief executives from the seven largest tobacco companies in the United States testified together before Congress for the first time.[1] Congressman Ron Wyden of Oregon began his questioning of the

† J.D., 2022, University of South Dakota Knudson School of Law; M.P.P., 2019, University of Minnesota, Humphrey School of Public Affairs; B.A., 2017, Augustana University. I could not have told this story without the help of my advisors, colleagues, friends, and family. Specifically, I want to thank the late Augustana Professor Peter Schotten, without whom I would not be in law school or anywhere near it. Dr. Schotten believed in me even when I gave him reason not to; I, like so many Augustana alumni, will be forever grateful to have known him. Thank you to Devan Seward for his generous feedback on this article, and more importantly, his enduring friendship. Thank you to my younger sister, Shaylee McCue, for keeping her ear to the ground—it never ceased to amaze me how much more I could learn from an intelligent and observant high school student than the so-called professionals. Special thanks to Professor Thomas Horton, Karen Baese, Terry McCue, Gigi Chawla, Michael McCue, Matthew Drake, and so many more. Lastly, thank you to my colleagues on the *South Dakota Law Review* for everything you did to bring this article to fruition.

1. Philip J. Hilts, *Tobacco Chiefs Say Cigarettes Aren't Addictive*, N.Y. TIMES (Apr. 15, 1994), https://www.nytimes.com/1994/04/15/us/tobacco-chiefs-say-cigarettes-aren-t-addictive.html.

executives rather bluntly: "Yes or no, do you believe nicotine is not addictive?"[2] One by one, each executive gave essentially the same answer: yes, they believed nicotine was not addictive.[3] History would not look too kindly on this testimony.[4] Just weeks after the famous 1994 hearing, a box of internal documents from the Brown & Williamson Tobacco Corporation was delivered to the University of California at San Francisco, with information revealing that the tobacco industry had long known their products were addictive and posed serious health risks.[5]

Fast forward some twenty-five years to February 5, 2020, when Congress again heard testimony from top executives on the issue of nicotine and addiction.[6] This time, however, the executives were not before the committee to talk about conventional combustible cigarettes; they were there to talk about a new method of nicotine consumption exploding in popularity across the world—electronic cigarettes.[7]

In stark contrast to the 1994 hearing, the five executives from the leading electronic cigarette manufacturers in the United States gave markedly different answers than their Big Tobacco predecessors on the question of whether they accepted that nicotine is addictive.[8] When asked this time whether nicotine is addictive, the executives responded with a resounding yes.[9] Congresswoman Diana DeGette of Colorado began her time by asking the executives, "Isn't it true that nicotine is addictive?"[10] K.C. Crosthwaite, CEO of Juul Labs, Inc.; Ricardo Oberlander, President & CEO of Reynolds American Inc.; Ryan Nivakoff, CEO of NJOY, LLC; Antoine Blonde, President of Fontem U.S.; and Jerry Loftin, President of Logic Technology Development, LLC, all answered in the affirmative, without hesitation.[11]

Perhaps even more striking was their testimony regarding the health effects of the tobacco products of the past.[12] Crosthwaite, whose company Juul Labs was the leading electronic cigarette manufacturer at the time, testified: "Combustible

2. *Regulation of Tobacco Products: Hearing Before the Subcomm. on Health and the Env't of the H. Comm. on Energy and Commerce*, 103rd Cong. (1994), https://senate.ucsf.edu/tobacco-ceo-statement-to-congress (last visited Oct. 12, 2021).

3. *Id.*

4. K. Michael Cummings et al., *The Cigarette Controversy*, 16 CANCER EPIDEMIOLOGY, BIOMARKERS AND PREVENTION 1070, 1070 (2007).

5. *Id.*

6. *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), https://energycommerce.house.gov/committee-activity/hearings/hearing-on-vaping-in-america-e-cigarette-manufacturers-impact-on-public (last visited Oct. 12, 2021).

7. *Id.*

8. *Id.*

9. *Id.*

10. *Id.*

11. *Id.*

12. *See generally* Written Testimony of K.C. Crosthwaite, CEO, Juul Labs, Inc., *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. 1 (2020), https://energycommerce.house.gov/sites/democrats.energycommerce.house.gov/files/documents/Testimony%20-%20Crosthwaite%2020200205.pdf [hereinafter Crosthwaite] (describing the harmful effects of smoking).

cigarettes remain the leading cause of preventable death in our country and worldwide. More than 34 million Americans still smoke. Each year, nearly half a million Americans die from smoking-related diseases—1 person every minute. The economic costs exceed $300 billion."[13] Clearly, these executives were not before Congress to deny the health risks of tobacco use—rather, they were there to try and change the increasingly negative public perception of the electronic cigarette industry and to show regulators that their products could actually produce a net *benefit* to public health.[14] Crosthwaite continued: "But research indicates that vapor products are substantially lower-risk than cigarettes and that many, if not most, adult smokers who try Juul products are able to successfully transition completely off of cigarettes to our products."[15] Time will tell whether their testimony was the beginning of a new era in the tobacco industry or if it was simply a revival of the forces that led Big Tobacco to unabashedly tell Congress twenty-five years ago that nicotine was not addictive when they knew that it was.[16]

The rise of electronic cigarettes has put government regulators and public health practitioners in a precarious position.[17] Smoking continues to be the leading cause of preventable death in the United States each year.[18] On the one hand, there is a plausible argument that policymakers should welcome, if not encourage, technological innovations that might reduce the risks of conventional tobacco use, even if those alternatives fail to eliminate the risks altogether.[19] On the other hand, there are legitimate concerns over the dearth of research on the

13. *Id.* at 2.

14. *See generally* Written Testimony of Ricardo Oberlander, President & CEO, Reynolds American Inc., *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. 1 (2020), https://energycommerce.house.gov/sites/democrats.energycommerce.house.gov/files/documents/Testimony%20-%20Oberlander%2020200205.pdf ("Over a decade ago, Reynolds set a goal to transform the tobacco market through innovative products that could make tobacco harm reduction a reality for adult smokers. Doing so requires us to provide consumer-acceptable products that may present less risk, including products in the vapor category."); Written testimony of Ryan Nivakoff, CEO, NJOY, LLC, *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. 1 (2020), https://energycommerce.house.gov/sites/democrats.energycommerce.house.gov/files/documents/Testimony%20-%20Nivakoff%2020200205.PDF ("The National Academies of Sciences, Engineering, and Medicine has said: 'complete switching from combustible tobacco cigarettes to e-cigarettes would be expected to reduce tobacco related health risk.'").

15. Crosthwaite, *supra* note 12.

16. *See* Cummings et al., *supra* note 4.

17. *See infra* notes 19, 20.

18. Melisa R. Creamer et al., *Tobacco Product Use and Cessation Indicators Among Adults—United States, 2018*, 68 CDC: MORBIDITY AND MORTALITY WKLY. REP. 1013, 1013 (2019).

19. *See, e.g.*, 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 [hereinafter FDA Press Release 2017] ("A key piece of the FDA's approach is demonstrating a greater awareness that nicotine—while highly addictive—is delivered through products that represent a continuum of risk and is most harmful when delivered through smoke particles in combustible cigarettes.").

long-term health effects of electronic cigarette use[20]—not to mention the fact that plots by the tobacco industry to market new products based on unfounded health claims are nothing new.[21] As policymakers have wrestled over whether the rise of electronic cigarette use should be cautiously embraced or outright condemned, the market for these products has undeniably exploded.[22] Despite what efforts there have been from regulators to get a handle on the electronic cigarette market since the products were first introduced, Americans—adults and youth alike—have taken to using electronic cigarettes in astounding numbers.[23] The long-term public health repercussions that may stem from the rise of electronic cigarette use remain to be seen.[24]

This paper will argue that the regulatory response—or lack thereof—to the electronic cigarette industry has put the United States in a dubious position, not far from where it was when the products were first introduced to the market over a decade ago.[25] The federal government has been inconsistent in its approach and too slow to respond to the rise of electronic cigarettes, and as a result, millions of U.S. youth have developed a nicotine addiction that could have been prevented.[26] It is time for the federal government to establish clear policy goals regarding electronic cigarettes and take decisive action to achieve those goals before it is too late.[27] Policymakers should work to prevent youth from ever using nicotine in the first place while remaining careful not to preclude adult smokers from potentially safer tobacco alternatives—albeit with hefty skepticism of unfounded health claims coming from actors inside the industry.[28] Part II will give a brief background on the rise of electronic cigarettes.[29] Part III will describe the attempts to address the introduction of electronic cigarettes to the United States

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20. NAT'L ACADS. OF SCIS., ENG'G, AND MED., PUB. HEALTH CONSEQUENCES OF E-CIGARETTES (Kathleen Stratton et al. eds., 2018), https://www.ncbi.nlm.nih.gov/books/NBK507163/ ("Taken together, the evidence reviewed by the committee suggests that e-cigarettes are not without physiological activity in humans, but the implications for long-term effects on morbidity and mortality are not yet clear.").

21. K. Michael Cummings & Robert N. Proctor, *The Changing Public Image of Smoking in the United States: 1964–2014*, 23 CANCER EPIDEMIOLOGY BIOMARKERS AND PREVENTION 32, 32 (2014). The filter found today in most conventional cigarettes is one such example:

> Cigarette sales declined in 1953 and the first part of 1954, but quickly rebounded as manufacturers rushed to introduce and market "filtered" cigarettes to allay health concerns. The emergence of the filter tip cigarette was a direct response to the publicity given to evidence linking smoking and cancer, and consumers reacted by shifting over to the new designs . . . . The advertised benefits of filters were illusory, however, given that smokers of filtered brands often inhaled as much or more tar, nicotine, and noxious gases as smokers of unfiltered cigarettes. Filters were not really even filters in any meaningful sense, since there was no such thing as "clean smoke." The industry had recognized this as early as the 1930s, but smokers were led to believe they were safer.

Id.

22. *See infra* Part II.B.
23. *See infra* Part II.B.
24. *See infra* Part IV.
25. *See infra* Part IV.
26. *See infra* Part II.B.2.
27. *See infra* Part II.B.2.
28. *See infra* Part II.B.
29. *See infra* Part II.

market.[30] Parts IV and V will address public health issues that have grown out of the United States' disjointed and tepid regulatory response to electronic cigarettes and conclude by outlining lessons for the future of electronic cigarette regulation.[31]

II. BACKGROUND

A. TOBACCO USE IN THE UNITED STATES

In 2018, approximately 49.1 million U.S. adults reported they were currently using any tobacco product.[32] More than eighty percent of tobacco users reported using traditional, combustible tobacco products such as cigarettes and cigars.[33] Over the past fifty-plus years, the United States has experienced significant declines in rates of adult tobacco use, which has been hailed as a tremendous success of organized public health initiatives.[34] Despite these declines, tobacco use continues to harm public health, with roughly 480,000 Americans dying from smoking combustible cigarettes each year.[35] Widespread tobacco use has more than just mortality costs: it is estimated that every year medical costs and losses in economic productivity due to smoking-related illnesses cost the United States upwards of $300 billion.[36]

Even though by the late 1950s medical science had established a clear link between smoking and the occurrence of cancer,[37] it was not until the beginning of the next decade that the American public first started to recognize and accept the potential adverse health effects of tobacco use.[38] Over the ensuing decades, private litigants brought hundreds of lawsuits against tobacco manufacturers

30. *See infra* Part III.

31. *See infra* Parts IV and V.

32. Creamer et al., *supra* note 18, at 1014.

33. *Id.*

34. *Id.* at 1015 ("The approximate two thirds decline in adult cigarette smoking prevalence that has occurred since 1965 represents a major public health success. In 2018, 13.7% of U.S. adults aged ≥18 years currently smoked cigarettes, the lowest prevalence recorded since 1965."); *see also* U.S. DEP'T OF HEALTH & HUM. SERV., THE HEALTH CONSEQUENCES OF SMOKING – 50 YEARS OF PROGRESS: A REPORT OF THE SURGEON GENERAL 3 (2019), https://www.cdc.gov/tobacco/data_statistics/sgr/50th-anniversary/index.htm ("Americans' collective view of smoking has been transformed from an accepted national pastime to a discouraged threat to individual and public health. Strong policies have largely driven cigarette smoking out of public view and public air space.").

35. CTR. 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#nation (last visited Oct. 12, 2021).

36. CTR. FOR DISEASE CONTROL AND PREVENTION, *Economic Trends in Tobacco*, https://www.cdc.gov/tobacco/data_statistics/fact_sheets/economics/econ_facts/index.htm (last visited Oct. 12, 2021) [hereinafter *Economic Trends in Tobacco*].

37. *See, e.g.*, Cummings et al., *supra* note 4, at 1071 (discussing landmark medical journal articles published in the 1950s that documented a link between smoking and cancer).

38. Cummings & Proctor, *supra* note 21, at 2 ("The 1964 report of the Surgeon General's Advisory Committee marks the beginning of a significant shift in public attitudes about smoking.") (citations omitted).

seeking damages related to smoking-related illnesses, but most of these efforts largely failed.[39] Individual plaintiffs found it difficult to overcome allegations from the tobacco industry that smokers themselves were largely responsible for their poor health outcomes.[40] Plaintiffs did not start to see success in the courts until the 1990s when state governments began to bring lawsuits against tobacco companies.[41] One of the first major legal achievements against the tobacco industry came in November of 1998, when forty-six states, five U.S. territories, and the District of Columbia reached a settlement—"The Master Settlement Agreement"—with four major cigarette manufacturers.[42] The Master Settlement Agreement was the largest civil litigation settlement in United States history, requiring the defendant tobacco companies to pay the settling states billions of dollars in damages annually, in perpetuity.[43]

While a detailed history of the lawsuits brought against the commercial tobacco industry is beyond the scope of this paper, many of the facts that emerged from that litigation animate the public skepticism that should be present in the emerging debate over electronic cigarettes.[44] The facts in *United States v. Philip Morris*,[45] a landmark case brought by the federal government alleging that tobacco companies had engaged in a decades-long conspiracy to cover up the risks of smoking, are particularly illustrative:

> The court found that Defendants engaged in a scheme to defraud smokers and potential smokers by (1) falsely denying the adverse health effects of smoking; (2) falsely denying that nicotine and smoking are addictive; (3) falsely denying that they manipulated cigarette design and composition so as to assure nicotine delivery levels that create and sustain addiction; (4) falsely representing that light and low tar cigarettes deliver less nicotine and tar and therefore present fewer health risks than full flavor cigarettes; (5) falsely denying that they market to youth; (6) falsely denying that secondhand smoke causes disease; and (7) suppressing documents, information, and research to prevent the public from learning the truth about these subjects and to avoid or limit liability in litigation.[46]

39. *See The Master Settlement Agreement: An Overview*, PUB. HEALTH L. CTR. 2 (2019) ("From the mid-1950s through 1994, individuals brought over 800 claims against cigarette manufacturers for damages related to the effects of smoking. However, the manufacturers, raising defenses such as contributory negligence and the individual responsibility of smokers, generally prevailed in these lawsuits.").

40. *Id.*

41. *Id.*

42. *Id.* at 1-2.

43. *Id.* at 2.

44. *See* United States v. Philip Morris USA Inc., 566 F.3d 1095 (D.C. Cir. 2009).

45. 566 F.3d 1095 (D.C. Cir. 2009).

46. *Id.* at 1108 (citations omitted).

Even with the billions of dollars paid out by Big Tobacco over the years to settle legal disputes, the industry continues to be profitable.[47] According to the Centers for Disease Control and Prevention, tobacco companies spent over eight billion dollars on cigarette and smokeless tobacco marketing in 2019 alone.[48] In the United States, almost 250 billion cigarettes are sold every year, with four companies accounting for more than ninety percent of those sales.[49]

B. ELECTRONIC CIGARETTES

Efforts to develop battery-powered, "smokeless," and ostensibly healthier alternatives to traditional combustible cigarettes can be found as early as the 1960s.[50] The modern precursor to the electronic cigarettes widely used today, however, has largely been attributed to a 2003 invention by a Chinese pharmacist named Hon Lik.[51] While modern electronic cigarettes come in a variety of shapes and sizes, the components and mechanics of the devices are relatively uniform and simple:

> E-cigarette devices are composed of a battery, a reservoir for holding a solution that typically contains nicotine, a heating element or an atomizer, and a mouthpiece through which the user puffs []. The device heats a liquid solution (often called e-liquid or e-juice) into an aerosol that is inhaled by the user. E-liquid typically uses propylene glycol and/or glycerin as a solvent for the nicotine and flavoring chemicals.[52]

Electronic cigarettes go by several different names among manufacturers and users, including "vapes," "vape pens," and "mods," to name a few.[53] Researchers often refer to the wide range of electronic cigarette products as "Electronic

47. Jennifer Maloney & Saabira Chaudhuri, *Against All Odds, the U.S. Tobacco Industry Is Rolling in Money*, WALL ST. J. (Apr. 23, 2017, 1:31 PM), https://www.wsj.com/articles/u-s-tobacco-industry-rebounds-from-its-near-death-experience-1492968698.

48. *Economic Trends in Tobacco*, *supra* note 36.

49. *Id.* The four companies are Philip Morris USA, Reynolds American Inc., ITG Brands, and Ligget. *Id.*

50. U.S. DEP'T OF HEALTH & HUM. SERV., *Chapter 1: Introduction, Conclusions, and Historical Background Relative to E-Cigarettes*, E-CIGARETTE USE AMONG YOUTH AND YOUNG ADULTS: A REPORT OF THE SURGEON GENERAL 10 (2019), https://www.cdc.gov/tobacco/data_statistics/sgr/e-cigarettes/index.htm#report [hereinafter E-CIGARETTE USE AMONG YOUTH] (noting patent application filed in 1963 for a battery powered nicotine delivery device).

51. *See* Sarah Boseley, *Hon Lik invented the e-cigarette to quit smoking – but now he's a dual user*, THE GUARDIAN (June 9, 2015, 1:24 PM), https://www.theguardian.com/society/2015/jun/09/hon-lik-e-cigarette-inventor-quit-smoking-dual-user. *But see* Lauren M. Dutra et al., *Philip Morris research on precursors to the modern e-cigarette since 1990*, 26 TOBACCO CONTROL 97-105 (2017) ("The technology for the modern e-cigarette did not originate solely in China in 2003; the idea that Hon Lik was the first person to develop a device that aerosolized a nicotine solution is an oversimplification of the history of the e-cigarette.").

52. E-CIGARETTE USE AMONG YOUTH, *supra* note 50, at 11.

53. CTR. FOR DISEASE CONTROL AND PREVENTION, *About Electronic Cigarettes (E-Cigarettes)*, https://www.cdc.gov/tobacco/basic_information/e-cigarettes/about-e-cigarettes.html (last visited Nov. 8, 2021).

Nicotine Delivery Systems" or "ENDS."[54] When first introduced to the United States market around 2007, electronic cigarettes were sold mostly online and in mall kiosks.[55] It was not long before the devices were sold in mass across the country in convenience stores, tobacco shops, large retail chains, and "vape shops."[56] Early on, blu, NJOY, and Logic were the three major electronic cigarette brands in the United States.[57] But no company's history parallels the rise of the United States electronic cigarette industry quite like that of Juul Labs, Inc.[58]

1. The JUUL

The company that eventually became Juul Labs began as a relatively small, San Francisco-based startup founded by Adam Bowen and James Monsees, two Stanford graduate students studying product design.[59] According to Juul, back in 2004, Bowen and Monsees expressed mutual interest to one another during a smoke break about developing an alternative to combustible cigarettes.[60] For their master's thesis presentation in June of 2005, Bowen and Monsees described an electronic cigarette they had created called "Ploom," a device they thought of as "the rational future of smoking."[61] The two described Ploom as a device that would allow users to get a nicotine fix without the social stigma associated with traditional smoking.[62] Bowen and Monsees expressed that through Ploom's design and attractive packaging, it could "take tobacco back to being a luxury good, not so much a drug delivery device."[63]

Ploom proved to be quite successful.[64] In just three years, Ploom was able to raise almost one million dollars in venture funding, which put the company's valuation at three million dollars by February of 2008.[65] Over the next seven years, Ploom raised millions more in funding, with the company releasing several

54. *Id.*

55. Daniel P. Giovenco, et al., *E-Cigarette Market Trends in Traditional U.S. Retail Channels, 2012-2013*, 17 NICOTINE & TOBACCO RSCH. 1279, 1279 (2015), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4683368/pdf/ntu282.pdf.

56. *Id.*

57. *Id.* at 1280.

58. *See infra* Part II.B.1.

59. *Our Founders' Story*, JUUL LABS: CO. NEWS (Feb. 27, 2019), https://www.juullabs.com/our-founders-story/.

60. *Id.*

61. Juul Labs, *Adam and James' Thesis Presentation*, YOUTUBE (Feb. 27, 2019), https://youtu.be/ZBDLqWCjsMM.

62. *Id.*

63. *Id.*

64. *See* Erin Brodwin, *The Precarious Path of E-Cig Startup Juul: From Silicon Valley Darling to $24 Billion Behemoth Under Criminal Investigation*, BUS. INSIDER (Oct. 31, 2019, 10:34 AM), https://www.businessinsider.com/juul-timeline-from-startup-to-tobacco-company-challenges-bans-2019-9#june-1-2015-pax-labs-launches-the-juul-with-a-party-in-new-york-city-5 [hereinafter *The Precarious Path of Juul*].

65. *Id.*

iterations of its tobacco vaporizers.[66] Ploom's success garnered the interest of traditional tobacco companies, and in February of 2015, Japan Tobacco International purchased the intellectual property rights and patents for Ploom's devices.[67] Bowen and Monsees had come a long way from their initial plans to disrupt the traditional tobacco industry.[68]

By June of 2015, Bowen and Monsees had rebranded Ploom as Pax Labs and released a new kind of electronic cigarette called the JUUL.[69] Piggybacking on the original Ploom design, JUUL is a buttonless device that measures three and a half inches long and closely resembles the silhouette of a flash drive, which heats disposable "pods" of highly concentrated, nicotine-infused liquid into a warm vapor that is inhaled by the user.[70] The pods were initially released in a variety of different flavors, including mint, cucumber, mango, menthol, fruit, and classic tobacco.[71] In 2017, the device was formally spun out from Pax Labs and made into an independent company operating under the name Juul Labs.[72]

The JUUL proved to be more popular than any of Bowen and Monsees's preceding vaporizer designs.[73] Sales of the JUUL soared by 700% in 2016 alone.[74] By November of the next year, JUUL was the most popular electronic cigarette on the market,[75] and by December 2018, "JUUL accounted for an estimated 76% of the $322.1 million total e-cigarettes sales that occurred that month in the United States."[76] Some have likened the JUUL's success to that of Apple, drawing comparisons between their shared focus on minimalist and simplified design.[77] Others have been far more critical; as it turned out, reducing the stigma associated with smoking appealed to more than just current cigarette users.[78]

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66. *Id.*

67. Press Release, Japan Tobacco International, JTI acquires "Ploom" Intellectual Property Rights from Ploom, Inc. (Feb. 16, 2015), https://www.jti.com/sites/default/files/press-releases/documents/2015/press-release-jti-ploom-final.pdf.

68. *See Our Founders' Story*, *supra* note 59.

69. *The Precarious Path of Juul*, *supra* note 64.

70. Amanda Capritto, *Juul vape: What Is It, Why Are Teens Addicted, And Is It Safe?*, CNET: HEALTH AND WELLNESS (Sept. 16, 2019, 2:59 PM), https://www.cnet.com/health/juul-what-is-it-how-does-it-work-and-is-it-safe/.

71. *Id.*

72. *The Precarious Path of Juul*, *supra* note 64.

73. *Id.*

74. *Id.*

75. *Id.*

76. Melisa R Creamer et al., *Tobacco Product Use Among High School Students — Youth Risk Behavior Survey, United States, 2019*, 69 CDC: MORBIDITY AND MORTALITY WKLY. REP. 56, 56 (2020), https://www.cdc.gov/mmwr/volumes/69/su/pdfs/su6901a7-H.pdf [hereinafter *Youth Risk Behavior Survey 2019*].

77. Melia Robinson, *The CEO of the 'Apple of vaping' explains why the comparison makes sense*, BUSINESS INSIDER (Aug. 26, 2015, 2:13 PM), https://www.businessinsider.com/pax-labs-apple-of-vaping-2016-8.

78. *See infra* Part II.B.2.

2. Youth Vaping

The allure of the JUUL and other electronic cigarette brands did not take long to reach young people across the United States.[79] "Juuling" quickly became a verb synonymous with "vaping."[80] From 2017 to 2018, there was a seventy-eight percent increase in electronic cigarette use among high school students and a forty-eight percent increase among middle school students.[81] Explanations for the rise in youth electronic cigarette use cite factors such as "advertising exposure, availability of youth-appealing flavors, curiosity, and social exposure through friends and others."[82]

In December of 2018, the United States Surgeon General officially declared that youth vaping had become an epidemic in the United States.[83] In declaring the epidemic, the Surgeon General warned parents of signs that their children may be vaping and cautioned of the potential harm the behavior could have on their health.[84] Early on, parents were often unaware their children may be vaping because the devices can look like flash drives or highlighters, and the vapor is mostly odorless and dissipates within seconds[85]—features which no doubt echo Ploom's early-stated goal of reducing smoking's usual stigma.[86] Concerns also began to circulate that youth who vape are far more likely to take up traditional tobacco smoking than those who do not.[87]

The day after the Surgeon General declared youth electronic cigarette use an epidemic in the United States, Altria—formerly Philip Morris, the company with the largest share of the U.S. cigarette market—offered $12.8 billion for a thirty-five percent stake in Juul Labs, putting Juul's total valuation at thirty-eight billion dollars.[88] The all-cash Juul/Altria deal was finalized on December 20, 2018, with

79. *See infra* notes 81-87.

80. *See generally* Jia Tolentino, *The Promise of Vaping and the Rise of JUUL*, NEW YORKER (May 14, 2018), https://www.newyorker.com/magazine/2018/05/14/the-promise-of-vaping-and-the-rise-of-juul ("To Juul (the brand has become a verb) is to inhale nicotine free from the seductively disgusting accoutrements of a cigarette: the tar, the carbon monoxide, the garbage mouth, the smell.").

81. Karen A. Cullen et al., *Use of Electronic Cigarettes and Any Tobacco Product Among Middle and High School Students—United States, 2011–2018*, 67 CDC: MORBIDITY AND MORTALITY WEEKLY REPORT 1276, 1276 (2018), https://www.cdc.gov/mmwr/volumes/67/wr/pdfs/mm6745a5-H.pdf ("The rise in e-cigarette use during 2017–2018 is likely because of the recent popularity of e-cigarettes shaped like a USB flash drive, such as JUUL; these products can be used discreetly, have a high nicotine content, and come in flavors that appeal to youths [].").

82. *Youth Risk Behavior Survey 2019*, *supra* note 76, at 56.

83. Press Release, U.S. Dep't of Health & Hum. Serv., Surgeon General releases advisory on E-cigarette epidemic among youth (Dec. 18, 2018), https://www.hhs.gov/about/news/2018/12/18/surgeon-general-releases-advisory-e-cigarette-epidemic-among-youth.html.

84. *Id.*

85. *See* Divya Ramamurthi et al., *JUUL and Other Stealth Vaporisers: Hiding the Habit From Parents and Teachers*, 28 TOBACCO CONTROL 610 (2019).

86. *See supra* note 62 and accompanying text.

87. Adam M. Leventhal et al., *Association of Electronic Cigarette Use With Initiation of Combustible Tobacco Product Smoking in Early Adolescence*, 314 JAMA 700 (2015).

88. Matt Richtel & Sheila Kaplan, *Juul May Get Billions in Deal With One of World's Largest Tobacco Companies*, N.Y. TIMES (Dec. 19, 2018), https://www.nytimes.com/2018/12/19/health/juul-altria-e-cigarettes.html.

Altria executives noting that the company was prepared to help Juul take on the U.S. Food and Drug Administration (FDA).[89] With Juul facing mounting scrutiny for its business practices and the role it may have played in the explosion of youth electronic cigarette use, the company would now have support from a tobacco industry titan all too familiar with the legal and regulatory waters Juul Labs is certain to face in the years to come.[90]

III. REGULATORY RESPONSE

A. EARLY FAILURES

The first major attempt by the federal government to control electronic cigarettes laid bare the dilemma regulators faced when the products were first introduced to the U.S. market; that is, if, how, and to what extent electronic cigarettes could be regulated under existing federal law.[91] In April of 2009, the FDA ordered that several shipments of electronic cigarettes be denied entry into the United States because electronic cigarettes constituted "adulterated, misbranded, or unapproved drug-device combinations" and could be denied entry to the U.S. market under the Federal Food, Drug, and Cosmetic Act (FDCA).[92] The electronic cigarette companies whose shipments were denied, Sottera, Inc. (doing business as "NJOY") and Smoking Everywhere, Inc., swiftly filed suit against the FDA.[93] The companies claimed the FDA lacked authority under the FDCA to regulate tobacco products marketed without claims of therapeutic effect (i.e., treatment for nicotine addiction) and that the FDA only had the authority to regulate electronic cigarettes under the Family Smoking Prevention and Tobacco Control Act of 2009 (Tobacco Control Act).[94] In a somewhat dismissive tone, the district court held in favor of NJOY and Smoking Everywhere and enjoined the FDA from regulating electronic cigarettes as drug/devices.[95]

The U.S. Court of Appeals for the D.C. Circuit affirmed in *Sottera, Inc. v. FDA*,[96] agreeing with the district court that the FDA lacked authority under the

89. 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.

90. *See* David T. Levy et al., *Altria-Juul Labs deal: why did it occur and what does it mean for the US nicotine delivery product market*, 29 TOBACCO CONTROL (SPECIAL COMMUNIC'N) 1, https://tobaccocontrol.bmj.com/content/29/e1/e171 ("Juul Labs has clear motivations for the merger. Besides the direct gain to Juul Labs' owners from the acquisition price, they can also benefit in the legal and regulatory sphere. With its vast experience, Altria can provide Juul Labs support in legal battles regarding patent infringement and consumer health claims.").

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

92. *Id.* at 893.

93. Smoking Everywhere, Inc. v. U.S. Food & Drug Admin., 680 F. Supp. 2d 62, 63 (D.D.C. 2010), *aff'd sub nom. Sottera*, 627 F.3d at 899.

94. *Id.* at 64, 66.

95. *Id.* at 78 ("This case appears to be yet another example of FDA's aggressive efforts to regulate recreational tobacco products as drugs or devices under the FDCA . . . . Unfortunately, its tenacious drive to maximize its regulatory power has resulted in its advocacy of an interpretation of the relevant law that I find, at first blush, to be unreasonable and unacceptable.").

96. 627 F.3d 891 (D.C. Cir. 2010).

FDCA to regulate electronic cigarettes as customarily marketed.[97] The D.C. Circuit reasoned that the FDA's asserted authority to regulate electronic cigarettes under the FDCA was, among other things, precluded by the Supreme Court's decision in *FDA v. Brown & Williamson Tobacco Corp*.[98] In *Brown & Williamson*, the Supreme Court held that the FDA could not regulate traditional tobacco products as customarily marketed under the FDCA, because in "[c]onsidering the FDCA as a whole, it [was] clear that Congress intended to exclude tobacco products from the FDA's jurisdiction."[99] Essentially, the Court found that if the FDA had the authority to regulate tobacco products under the FDCA, the agency would be forced to ban tobacco because the FDCA generally requires the FDA to only approve products that are deemed safe and effective.[100] A complete ban of tobacco products, the Court believed, would be at odds with the United States' historical approach to tobacco.[101] Writing for the majority in *Brown & Williamson*, Justice O'Connor had little trouble rejecting the suggestion that Congress had ever intended to ban tobacco:

> Congress, however, has foreclosed the removal of tobacco products from the market. A provision of the United States Code currently in force states that "[t]he marketing of tobacco constitutes one of the greatest basic industries of the United States with ramifying activities which directly affect interstate and foreign commerce at every point, and stable conditions therein are necessary to the general welfare." 7 U.S.C. § 1311(a). More importantly, Congress has directly addressed the problem of tobacco and health through legislation on six occasions since 1965.[102]

With respect to electronic cigarettes, the D.C. Circuit held in *Sottera* that a proper reading of the *Brown & Williamson* decision demonstrated "that the FDA lacks FDCA drug/device authority to regulate all tobacco products marketed without claims of therapeutic effect, i.e., as customarily marketed."[103] In other words, as long as electronic cigarette manufacturers do not market their products for therapeutic uses, the products cannot be regulated under the FDCA.[104]

The court in *Sottera* held that the FDA's authority to regulate electronic cigarettes was provided by the Tobacco Control Act, which was passed by Congress to "fill the regulatory gap identified in *Brown & Williamson.*"[105] In its decision, the D.C. Circuit specifically set aside the FDA's fears of a regulatory

97. *Id.* at 895-96.
98. *Id.* (citing Food & Drug Admin. v. Brown & Williamson Tobacco Corp., 529 U.S. 120 (2000)).
99. *Brown & Williamson*, 529 U.S. at 142.
100. *Id.* at 134-35.
101. *Id.* at 137.
102. *Id.*
103. *Sottera*, 627 F.3d at 895.
104. *Id.*
105. *Id.* at 894.

void that might arise if the agency were confined to exercising its power under the Tobacco Control Act:

> The FDA has also offered a consequentialist argument, namely, that understanding *Brown & Williamson* in this fashion leaves the FDA severely thwarted in any effort to nudge e-cigarettes toward relatively healthful forms (or at least away from relatively unhealthful ones). Whether such a consequentialist argument should play any role in our interpretation of *Brown & Williamson* is questionable, but no matter. In fact the Tobacco Act gives the FDA broad regulatory authority over tobacco products . . . .[106]

The FDA's concerns proved to be well-founded, as not much progress was made in terms of federal electronic cigarette regulation in the years following the decision.[107] While, as the D.C. Circuit noted, the Tobacco Control Act gave the FDA broad authority to restrict the marketing of tobacco products,[108] regulations deeming electronic cigarettes as tobacco products subject to the Act—"The Deeming Rule"—were not officially promulgated by the FDA until 2016.[109] That is, from the *Sottera* decision in 2010, to when the Deeming Rule was announced in 2016, the FDA had essentially no ability to regulate electronic cigarettes whatsoever.[110] In those years, electronic cigarettes only grew in popularity.[111] From 2011 to 2015, electronic cigarette use by middle- and high school-aged students grew roughly 900% in the United States.[112]

Then came further delays.[113] Technically, when the Deeming Rule was set to go into effect in August of 2016, all electronic cigarettes on the market would have been immediately noncompliant with the statute.[114] Because of this, the FDA used its discretion to give electronic cigarette manufacturers up to twenty-four months to submit for market authorization before the agency would pursue enforcement.[115]

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106. *Id.* at 898.

107. *See* Katie Thomas & Sheila Kaplan, *E-Cigarettes Went Unchecked in 10 Years of Federal Inaction*, N.Y. TIMES (Oct. 14, 2019), https://www.nytimes.com/2019/10/14/health/vaping-e-cigarettes-fda.html.

108. *See* 21 U.S.C.A. § 387j (Westlaw through Pub. L. 116-193); *see also* U.S. FOOD & DRUG ADMIN., *Family Smoking Prevention and Tobacco Control Act – An Overview*, https://www.fda.gov/tobacco-products/rules-regulations-and-guidance/family-smoking-prevention-and-tobacco-control-act-overview (last visited Nov. 27, 2020) (giving an overview of main provisions of the Tobacco Control Act).

109. Deeming Rule, 81 Fed. Reg. 28,974-01, 28,976 (May 10, 2016).

110. *Id.*

111. *See, e.g.*, Giovenco et al., *supra* note 55, at 1279 ("E-cigarette sales more than doubled between 2012 and 2013, from $273.6 million to $636.2 million, respectively.").

112. U.S. DEP'T HEALTH & HUM. SERV., *Surgeon General's Advisory on E-cigarette Use Among Youth* (2018), https://e-cigarettes.surgeongeneral.gov/documents/surgeon-generals-advisory-on-e-cigarette-use-among-youth-2018.pdf.

113. *See* Am. Acad. of Pediatrics v. Food & Drug Admin., 379 F. Supp. 3d 461, 471 (D. Md. 2019).

114. *Id.*

115. *Id.*

But under new leadership in July of 2017, the FDA announced it would take a new approach to tobacco and nicotine product regulation.[116] The new approach posited that nicotine, while addictive, can be delivered through "products that represent a continuum of risk," and with that in mind, the FDA would be seeking to strike "an appropriate balance between regulation and encouraging development of innovative tobacco products that may be less dangerous than cigarettes . . . ."[117] The FDA would go on to announce in August of 2017 that the agency would be further deferring enforcement of the premarket review requirements for most electronic cigarette products until 2022.[118] In other words, electronic cigarettes would be permitted to remain on the market, without FDA intervention, for nearly four more years.[119] The shift in priorities by the newly appointed FDA Commissioner was criticized by some as an attempt by the FDA to cozy up to the tobacco industry; apparently, the new Commissioner had previously served on the board of a vape lounge company.[120]

Several anti-smoking groups successfully challenged the August 2017 extension in federal court; the court ordered that electronic cigarette manufacturers would have until May of 2020 to submit applications to the FDA for review.[121] Facing mounting evidence that youth electronic cigarette use was continuing to ascend at an alarming rate, the FDA began to backtrack on the new approach to tobacco regulation they had publicized just a year earlier.[122] In the wake of the court order, the FDA announced that it would do more to stem the "epidemic of use of e-cigs among teens" and that the agency would "re-visit the compliance policy that we announced last summer to extend the application compliance periods for certain deemed products, including and especially the e-cigarettes . . . ."[123]

With electronic cigarettes finally subject to the FDA's authority under the Tobacco Control Act, manufacturers must register with the FDA, submit a list of product ingredients, include health warnings on their packaging and advertising, and perhaps most importantly, obtain premarket authorization before introducing new products to the market.[124] The premarket review process for new tobacco products is fairly convoluted,[125] but essentially requires the FDA to look at

116. FDA Press Release 2017, *supra* note 19.

117. *Id.*

118. *Am. Acad. of Pediatrics*, 379 F. Supp. 3d at 472.

119. *Id.*

120. *See Senators Slam FDA Nominee Gottlieb As Being Too 'Cozy' With Big Pharma To Combat Opioid Epidemic*, FORBES (Apr. 4, 2017, 3:57 PM), https://www.forbes.com/sites/ritarubin/2017/04/04/senators-slam-fda-nominee-gottlieb-as-being-too-cozy-with-big-pharma-to-combat-opioid-epidemic/?sh=4b5daecd5c3a.

121. Am. Acad. of Pediatrics v. Food & Drug Admin., 399 F. Supp. 3d 479, 481 (D. Md. 2019), *appeal dismissed sub nom.* In re Cigar Ass'n of Am., 812 F. App'x 128 (4th Cir. 2020).

122. Press Release, 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).

123. *Id.*

124. *Am. Acad. of Pediatrics*, 379 F. Supp. 3d at 470-71.

125. *See* U.S. FOOD & DRUG ADMIN., *Premarket Tobacco Product Applications*, https://www.fda.gov/tobacco-products/market-and-distribute-tobacco-product/premarket-tobacco-product-applications (last visited Oct. 14, 2021).

electronic cigarettes and determine, among other things, whether "permitting such tobacco product to be marketed would be appropriate for the protection of the public health."[126] The determination must take into account the "risks and benefits to the population as a whole, including users and nonusers of the tobacco product" and "the increased or decreased likelihood that existing users of tobacco products will stop using such products; and [] the increased or decreased likelihood that those who do not use tobacco products will start using such products."[127] Products that the FDA determines fail the statutory standard can face removal from the market.[128] Juul Labs submitted their Premarket Tobacco Product Application to the FDA in July of 2020.[129]

B. SIGNS OF PROGRESS

In the wake of the Deeming Rule, the FDA was tasked with reviewing more than 6.5 million premarket review applications, most of which were for electronic cigarettes.[130] In September of 2021, the FDA announced that many of these applications had been denied because of the threats electronic cigarettes pose to youth:

> We've made significant progress . . . working diligently to better understand these products and, as of today, taking action on about 93% of the total timely-submitted applications. This includes issuing Marketing Denial Orders (MDO) for more than 946,000 flavored [electronic cigarettes] because their applications lacked sufficient evidence that they have a benefit to adult smokers sufficient to overcome the public health threat posed by the well-documented, alarming levels of youth use of such products.[131]

As of October 12, 2021, the agency has yet to announce a decision on Juul's application.[132]

Aside from the lengthy FDA review process, there have been a few relatively successful regulatory efforts of electronic cigarettes in the years since the federal government publicly acknowledged that the products might pose a critical threat to public health.[133] For example, in December of 2019, legislation was enacted

126. 21 U.S.C § 387j(c)(2)(A).

127. 21 U.S.C § 387j(c)(4).

128. 21 U.S.C § 387j(d).

129. *See Juul labs Submits Premarket Tobacco Product Application to the U.S. Food and Drug Administration for the JUUL System*, JUUL LABS: CO. NEWS (July 30, 2020), https://www.juullabs.com/juul-labs-submits-premarket-tobacco-product-application/.

130. Statement from Janet Woodcock, M.D., FDA Makes Significant Progress in Science-Based Public Health Application Review, Taking Action on Over 90% of More Than 6.5 Million 'Deemed' New Tobacco Products Submitted, U.S. FOOD & DRUG ADMIN. (Sept. 9, 2021), https://www.fda.gov/news-events/press-announcements/fda-makes-significant-progress-science-based-public-health-application-review-taking-action-over-90.

131. *Id.*

132. Matt Richtel, *F.D.A. Delays Decision on Juul's E-Cigarettes but Orders Others Off the Market*, N.Y. TIMES (Oct. 12, 2021), https://www.nytimes.com/2021/09/09/health/fda-e-cigarettes-vaping.html.

133. *See infra* notes 134-142.

amending the FDCA and raising the minimum tobacco purchase age from eighteen to twenty-one nationwide.[134] The change in federal law was the culmination of the "Tobacco 21" movement, a coalition that since 2012 had been able to successfully lobby state and local governments across the country to make changes to the minimum tobacco purchase age.[135] The change was long overdue in the eyes of most of the public—as early as 2015, nearly three in four Americans supported raising the minimum purchase age to twenty-one.[136] Public health practitioners have hailed the change as a step in the right direction towards curbing youth smoking; studies have shown that raising the minimum tobacco purchase age can lead to nearly fifty percent reductions in smoking rates among high school students.[137] Tobacco 21 laws disrupt the electronic cigarette supply chain for high school students because many people who purchase tobacco for underage students are still in high school themselves.[138]

The FDA took another step to address the rise of electronic cigarette use in January of 2020 when it unveiled what was effectively a nationwide ban on most flavored electronic cigarette products.[139] Under the policy, any flavored, cartridge-based electronic cigarette products, other than tobacco and menthol flavors, would be subject to FDA enforcement action.[140] Underlying the policy was a recognition that youth preference for tobacco and menthol flavors was much lower than that for mint and fruit flavored products.[141] The change seemed to be of little surprise to the industry: Juul removed most of its flavor options from the market two months before the policy was even announced.[142]

Companies like Juul have, for the most part, evaded stringent federal regulation, but that has not kept critics of electronic cigarettes from seeking to hold the industry accountable through the courts.[143] Numerous lawsuits have been

134. U.S. FOOD & DRUG ADMIN., *Newly Signed Legislation Raises Federal Minimum Age of Sale of Tobacco Products to 21*, https://www.fda.gov/tobacco-products/ctp-newsroom/newly-signed-legislation-raises-federal-minimum-age-sale-tobacco-products-21 (last visited Nov. 8, 2020).

135. Stephanie R. Morain et al., *Have Tobacco 21 Laws Come of Age?*, N. ENGL. J. MED. PERSPECTIVE (Apr. 28, 2016), https://www.nejm.org/doi/full/10.1056/NEJMp1603294.

136. Brian A. King et al., *Attitudes Toward Raising the Minimum Age of Sale for Tobacco Among U.S. Adults*, 49 AM. J. OF PREVENTIVE MED. 583, 583 (2015).

137. Shari Kessel Schneider et al., *Community reductions in youth smoking after raising the minimum tobacco sales age to 21*, 25 TOBACCO CONTROL 355, 355 (2016).

138. *Id.* at 358.

139. Erika Edwards, *Federal Flavor Ban Goes Into Effect Thursday, But Many Flavored Vape Products Will Still be Available*, NBC NEWS (Feb. 5, 2020, 11:29 AM), https://www.nbcnews.com/health/vaping/federal-flavor-ban-goes-effect-thursday-many-flavored-vape-products-n1130466.

140. Press Release, U.S. Food & Drug Admin., FDA finalizes enforcement policy on unauthorized flavored cartridge-based e-cigarettes that appeal to children, including fruit and mint (Jan. 2, 2020), https://www.fda.gov/news-events/press-announcements/fda-finalizes-enforcement-policy-unauthorized-flavored-cartridge-based-e-cigarettes-appeal-children [hereinafter FDA Flavor Ban].

141. *Id.*

142. Erika Edwards, *Juul stops selling mint ahead of anticipated federal ban on most e-cigarette flavors*, NBC NEWS (Nov. 7, 2019, 2:30 PM), https://www.nbcnews.com/health/vaping/juul-stops-selling-mint-ahead-anticipated-federal-ban-most-e-n1077211.

143. *See* Sheila Kaplan, *Juul to Pay $40 Million to Settle N.C. Vaping Case*, N.Y. TIMES (June 28, 2021), https://www.nytimes.com/2021/06/28/health/juul-vaping-settlement-north-carolina.html.

filed against Juul Labs with allegations that the company intentionally marketed its products to youth through targeted advertising campaigns.[144] Reminiscent of the legal march against Big Tobacco in the 1990s, it does appear the dominos have begun to fall for Juul.[145]

For example, in February of 2020, the Massachusetts Attorney General filed a lawsuit against Juul seeking damages for the costs the state has incurred in combating the rise of youth vaping.[146] In the complaint, the state alleged that Juul Labs had knowingly and intentionally chosen to market its products with models and images specifically intended for a youth audience.[147] The state alleged that Juul "explicitly identified its target audience as the 'cool crowd,' a demographic of young people who were 'fashionable, urban with a vibrant life,' and 'enjoy[ed] going out to shows and events.'"[148] Juul Labs has also been sued by the State of Illinois on allegations that the company misrepresented the level of nicotine in its products and misled the public by characterizing the JUUL as a smoking cessation device.[149] School districts across the country have also joined the legal fight, claiming that educational resources have been strained by the efforts necessary to curb vaping by students during school.[150] For example, to address the problem of vaping during schools, some districts have had to install vape mist sensors in bathrooms, remove doors from bathroom stalls, hire additional staff, and pay for programs to educate students on nicotine addiction.[151]

As of October 1, 2021, Juul is facing lawsuits from at least thirteen states, thousands of municipal governments, and private plaintiffs.[152] Many of those cases have been consolidated before a single U.S. District Court Judge in the Northern District of California, and it appears that at least eighteen of the bellwether cases are prepared to go forward on various legal theories.[153] In June of 2021, North Carolina Attorney General Josh Stein announced that the state had reached the first major settlement with Juul for its role in the youth vaping

144. *See* Kaplan, *supra* note 143.

145. *See infra* notes 146-150.

146. OFF. ATT'Y GEN. MAURA HEALEY, *Attorney General's Office Lawsuit Against JUUL*, https://www.mass.gov/lists/attorney-generals-office-lawsuit-against-juul (last visited Oct. 14, 2021).

147. Complaint at 15, Massachusetts v. Juul Labs, Inc., (Mass. Dist. Ct. 2020) (available at https://www.mass.gov/doc/juul-complaint/download).

148. *Id.* at 2.

149. Press Release, Illinois Attorney General Kwame Raoul, Attorney General Raoul files lawsuit against Juul Labs (Dec. 12, 2019), https://illinoisattorneygeneral.gov/pressroom/2019_12/20191212.html.

150. Adeel Hassan, *Juul Is Sued by School Districts That Say Vaping Is a Dangerous Drain on Their Resources*, N.Y. TIMES (Nov. 20, 2019), https://www.nytimes.com/2019/10/07/us/juul-vaping-schools.html.

151. *Id.*

152. Kaplan, *supra* note 143.

153. Brendan Pierson, *Juul directors, Altria must face bellwether lawsuits - judge*, REUTERS (July 23, 2021 1:50 PM), https://www.reuters.com/legal/litigation/juul-directors-altria-must-face-bellwether-lawsuits-judge-2021-07-23/; *see also* Order On Motions To Dismiss Personal Injury Bellwether Complaint at 42-43, In Re: Juul Labs, Inc., Marketing Sales Practice And Products Liability Litigation (N.D. Cal. 2021) (Case No. 19-md-02913-WHO) (available at https://fingfx.thomsonreuters.com/gfx/legaldocs/zjpqkqendpx/072221%20—%20ND%20Cal%20—%20In%20re%20Juul%20Labs%20decision.pdf) (denying in part and granting in part defendant's motion to dismiss).

epidemic.[154] The settlement, valued at forty million dollars, allowed Juul to escape without admitting any wrongdoing or liability but placed restrictions on the company's ability to market its products going forward.[155]

Juul is also under fire from the Federal Trade Commission for its dealings with Altria.[156] On April 1, 2020, the FTC announced that it was filing an administrative complaint seeking to unwind the 2018 Juul/Altria purchase agreement on the grounds that Altria and Juul Labs had entered into a series of anticompetitive agreements in violation of federal antitrust laws.[157] At the trial before an administrative law judge in June of 2021, the FTC argued that Altria had unlawfully removed its own electronic cigarette products from the market while in negotiations with Juul.[158] Altria and Juul Labs have denied the allegations, with Altria maintaining that its own electronic cigarettes were a failure and unrelated to its dealings with Juul.[159] Juul and Altria are also defending against identical claims from various private plaintiffs.[160]

IV. CONSEQUENCES

The federal response to the rise of electronic cigarettes has been slow, inconsistent, and largely ineffective.[161] For over a decade, states have been left mostly on their own and without federal support to address a serious and uncertain public health threat.[162] The bungled federal response to electronic cigarettes has not been without consequences.[163]

The slow federal regulatory response to the electronic cigarette industry has created a new generation of nicotine addicts.[164] While the flavor ban that went

154. Press Release, Office of Attorney General Josh Stein, Attorney General Stein Reaches Agreement with JUUL for $40 Million and Drastic Business Changes (June 28, 2021), https://ncdoj.gov/attorney-general-stein-reaches-agreement-with-juul-for-40-million-and-drastic-business-changes/.

155. *See* Final Consent Judgment, North Carolina v. Juul Labs, Inc. (2021) (No. 19-CVS-2885) (available at https://ncdoj.gov/wp-content/uploads/2021/06/2021-06-28-JUUL-Consent-Judgment.pdf).

156. *See* Press Release, Federal Trade Commission, FTC Sues to Unwind Altria's $12.8 Billion Investment in Competitor JUUL (Apr. 1, 2020), https://www.ftc.gov/news-events/press-releases/2020/04/ftc-sues-unwind-altrias-128-billion-investment-competitor-juul.

157. *Id.*

158. Jennifer Maloney, *Altria-Juul Deal Goes to Trial*, WALL ST. J. (June 2, 2021 5:46 PM), https://www.wsj.com/articles/altria-juul-deal-goes-to-trial-11622632516.

159. *See generally* Answer and Defenses of Respondent Juul Labs, Inc., In the Matter of Altria Group, Inc. and JUUL Labs, Inc. (2020) (No. 9393) (available at https://www.ftc.gov/system/files/documents/cases/d09393_r_jli_answer_and_defenses_public599011.pdf) (denying allegations).

160. Order on Motion to Compel and Motions to Dismiss, In re JUUL Labs, Inc., Antitrust Litigation (2021) (No. 20-cv-02345-WHO) (available at https://www.motleyrice.com/sites/default/files/documents/Antitrust/JUUL%20ECF%20270%20-%20MTD%20Decision.pdf).

161. *See supra* Part III.

162. *See* C K Gourdet et al., *A Baseline Understanding of State Laws Governing E-Cigarettes*, 23 TOBACCO CONTROL 37, 39 (2014).

163. *See Youth Risk Behavior Survey 2019*, *supra* note 76, at 56.

164. *Id.*

into effect in February of 2020 was a step in the right direction towards curbing youth vaping, the many loopholes carved into the policy—loopholes that some might characterize as capitulations to the powerful vape retailers lobby—have left teens with plenty of options to continue to support their addiction.[165] The flavor ban only covered "cartridge-based" electronic cigarettes, which had the effect of allowing mint and other youth appealing flavors to continue to be sold so long as the devices are designed to be disposable as soon as the nicotine-infused liquid runs dry.[166] Disposable electronic cigarettes available for sale, such as the "Puff Bar," come in flavors like lemon ice, blueberry ice, and watermelon, to name a few.[167] While the JUUL remains front and center as the target of what federal regulatory efforts there have been, smaller companies marketing JUUL lookalikes can fly under the radar.[168] In July of 2020, the FDA issued warning letters to a number of these disposable electronic cigarette companies,[169] but it is unclear whether any serious steps are being taken to remove the products from the market.[170] Puff Bar appears to have overtaken the JUUL as the most popular electronic cigarette among youth.[171]

We have also seen what kind of public health crises might be on the horizon if more is not done to get a handle on electronic cigarettes.[172] In the fall of 2019, the CDC began reporting on an outbreak of severe lung illnesses associated with the use of electronic cigarettes and other vape products.[173] The outbreak came to

165. Sheila Kaplan, *Teens Find a Big Loophole in the New Flavored Vaping Ban*, N.Y. TIMES (Feb. 12, 2020), https://www.nytimes.com/2020/01/31/health/vaping-flavors-disposable.html.

166. *See* FDA Flavor Ban, *supra* note 140. When the policy was announced, the FDA attempted to justify its limited scope:

> By not prioritizing enforcement against other flavored ENDS products in the same way as flavored cartridge-based ENDS products, the FDA has attempted to balance the public health concerns related to youth use of ENDS products with considerations regarding addicted adult cigarette smokers who may try to use ENDS products to transition away from combustible tobacco products.

Id. Under the Biden Administration, it does seem the FDA has grown more hostile towards flavored electronic cigarettes, as the agency has denied premarket applications for many of the flavored products. *See* Woodcock *supra* note 130.

167. *See* PUFF BAR, puffbar.com (last visited Oct. 14, 2021); *see also* Sheila Kaplan, *Lawmakers Say Puff Bar Used Pandemic to Market to Teens*, N.Y. TIMES (June 2, 2020), https://www.nytimes.com/2020/06/02/health/puff-bar-teens.html (listing flavors sold by Puff Bar).

168. *But see* 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 (noting that the FDA sent warning letters to several smaller companies selling ENDS targeted towards U.S. youths).

169. *Id.*

170. *See How companies like Puff Bar have avoided FDA regulation: "The industry can innovate around it"*, CBS NEWS (Dec. 15, 2021, 11:21 AM), https://www.cbsnews.com/news/puff-bar-fda-regulation-loopholes/ (noting steps by Puff Bar to skirt FDA restrictions on flavored electronic cigarettes).

171. Press Release, U.S. Food & Drug Admin., Youth E-cigarette Use Remains Serious Public Health Concern Amid COVID-19 Pandemic (Sept. 30, 2021), https://www.fda.gov/news-events/press-announcements/youth-e-cigarette-use-remains-serious-public-health-concern-amid-covid-19-pandemic.

172. *See* Sydney Lupkin & Anna Maria Barry-Jester, *Mysterious Vaping Lung Injuries May Have Flown Under Regulatory Radar*, KAISER HEALTH NEWS (Aug. 27, 2019), https://khn.org/news/mysterious-vaping-lung-injuries-may-have-flown-under-regulatory-radar/.

173. *Id.*

the attention of public health officials when an alarming number of patients, many of them young adults, began reporting to emergency rooms with complaints of shortness of breath and other flu-like symptoms; the patients all reported recent use of a variety of different vapor products.[174] According to one tracker, by January of 2020, 2,602 cases and fifty-nine deaths had been connected to the vape-related illness nationwide.[175]

The CDC later found that many of the cases were connected to the use of illicit THC-containing electronic cigarettes sold on the street, which had been infused with dangerous levels of Vitamin E acetate.[176] While this outbreak may not have been directly connected to the use of common electronic cigarettes sold in stores across the country, the confusion and alarm raised by the illness foreshadow the crises that can arise when large numbers of individuals consume unregulated products with scarce scientific data on their potential long term health effects.[177]

The CDC's public response to the outbreak was harshly criticized by electronic cigarette companies.[178] In a letter to the FDA in June of 2020, a Juul Labs executive posited that by conflating the types of electronic cigarettes responsible for the outbreak, the federal government had caused unnecessary and dangerous confusion among the public; Juul cited a rise in cigarette sales in the months during and after the outbreak as evidence that the CDC's messaging had led many adult smokers to believe electronic cigarettes were more dangerous than combustible cigarettes.[179] Given the significant financial relationship Juul Labs has with one of the country's largest combustible cigarette manufacturers, Altria, Juul's concern that its customers might be switching back to combustible cigarettes is particularly ironic.[180]

V. CONCLUSION

Since the introduction of electronic cigarettes to the United States over a decade ago, the federal government has time and time again failed to comprehensively address this incredibly important issue of consumer protection.[181] The United States' experience dealing with anti-consumer behavior

174. CTR. FOR DISEASE CONTROL AND PREVENTION, *Outbreak of Lung Injury Associated with the Use of E-Cigarette, or Vaping, Products*, https://www.cdc.gov/tobacco/basic_information/e-cigarettes/severe-lung-disease.html#overview (last visited Oct. 16, 2021) [hereinafter *Outbreak of Lung Injury Associated with the Use of E-Cigarette, or Vaping, Products*].

175. Jonathan Corum, *Vaping Illness Tracker*, N.Y. TIMES (JAN. 13, 2020), https://www.nytimes.com/interactive/2020/health/vaping-illness-tracker-evali.html.

176. *Outbreak of Lung Injury Associated with the Use of E-Cigarette, or Vaping, Products*, *supra* note 174.

177. *See id.*

178. *See* Letter Re: Docket No. FDA-2020-N-0597; Request for Information on Vaping Products Associated with Lung Injuries from Jose Luis Murillo, Chief Regulatory Officer, Juul Labs, Inc., to Dockets Management Staff, Food and Drug Administration (June 19, 2020) (on file with author).

179. *Id.*

180. *See* Richtel & Kaplan, *supra* note 88.

181. *See supra* Part III.

by the commercial tobacco industry throughout the twentieth century should have put regulators on notice of the kind of urgency and suspicion required to effectively deal with emerging issues related to nicotine products.[182] Instead, the United States has consistently been a step behind and has seen nearly fifteen years of inaction and half-baked attempts to confront the rise of the electronic cigarette industry.[183] Companies like Juul Labs have been able to capitalize on this regulatory void, reaping millions of dollars in profits and recruiting a new generation of nicotine addicts in the process.[184] Admittedly, the federal government is not exactly well suited for quick and decisive action. But on the issue of electronic cigarettes, regulators have seen this movie before, and future tobacco policy can and should be informed by lessons of the past.[185]

It is crucial that the federal government pursue a clearer and more consistent communications strategy around the consequences of electronic cigarette use.[186] With the adoption of the Deeming Rule, the FDA now has broad authority to regulate electronic cigarettes, and the Biden administration should be as transparent as possible regarding how and when it plans to exercise that authority.[187] While it may not be wise to completely preclude adult smokers from making the switch to electronic cigarettes—especially if it turns out that use of the devices is at least somewhat safer than the use of combustible cigarettes—policymakers should still pursue policies that discourage youth from ever starting to use nicotine in the first place.[188] We can walk and chew gum at the same time.

Raising the federal minimum tobacco purchase age was a step in the right direction, as it left a potentially safer alternative to combustible cigarettes available to adult smokers while cutting off a clear supply line to younger generations.[189] The FDA, through the premarket review process, can vastly cut down on the number of electronic cigarettes available for sale to the public.[190] An outright ban of electronic cigarettes may go too far and cut off realistic opportunities to move adult smokers onto potentially safer products, but limiting the variety of products available, especially those with youth appealing flavors, would make it easier for the federal government to monitor developments in the industry and ensure compliance from manufacturers.[191] Electronic cigarettes pose difficult questions of law and policy, but the last two decades have shown that it is better to proceed with caution than to not proceed at all.[192]

182. *See supra* Part I.
183. *See supra* Part III.
184. *See supra* Part II.B.2.
185. *See supra* Part I.
186. *See supra* Part IV (discussing consequences of the lack of regulation regarding electronic cigarettes).
187. *See* Deeming Rule, *supra* note 109.
188. *See supra* Part II.B.2.
189. *See* Shari Kessel Schneider et al., *supra* note 137.
190. *See* Shari Kessel Schneider et al., *supra* note 137.
191. *See* Edwards, *supra* note 139.
192. *See supra* Part III.B.

One would be remiss not to note the particularly high risk the rise of electronic cigarettes might pose to communities of color in the United States.[193] The tobacco industry has a long history of purposefully and consciously targeting African Americans with particular forms of advertising, as it did throughout the twentieth century with menthol cigarettes.[194] Policymakers seemingly have begun to confront some of the disproportionate harms that have fallen on African Americans as a result of Big Tobacco's marketing ploys, and the unique experience of these communities should not be overlooked as the federal government develops further regulation of electronic cigarettes.[195]

Given the adverse health consequences associated with traditional tobacco use, it is reasonable to assert that nicotine products that present a lower continuum of risk should be given a chance.[196] It is neither reasonable nor good policy, however, to let an industry notorious for deceptively marketing dangerous products go unchecked by the federal government for years.[197] The federal government must learn from its history of mistakes and act decisively to comprehensively address the rise of electronic cigarette use before it is too late.[198] It's better late than never.

193. *See* Phillip S. Gardiner, *The African Americanization of menthol cigarette use in the United States*, 6 NICOTINE & TOBACCO RSCH 55, 55 (2004) ("Through the use of television and other advertising media, coupled with culturally tailored images and messages, the tobacco industry 'African Americanized' menthol cigarettes.").

194. *Id.*

195. *See* Sheila Kaplan, *Menthol Cigarettes Kill Many Black People. A Ban May Finally Be Near.*, N.Y. TIMES (Mar. 22, 2021), https://www.nytimes.com/2021/03/22/health/methol-smoking-ban.html ("The banning of menthol cigarettes, the mint-flavored products that have been aggressively marketed to Black Americans, has long been an elusive goal for public health regulators. . . . There is now growing momentum in Congress to enact a ban.").

196. *See* FDA Press Release 2017, *supra* note 19.

197. *See supra* Part I (discussing the regulation of the tobacco industry).

198. *See supra* Part I (discussing the regulation of the tobacco industry and the human toll of tobacco use).