

TOBACCO REBORN: THE RISE OF E-CIGARETTES AND REGULATORY APPROACHES

by
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This Article examines e-cigarettes, FDA-regulated products which heat nicotine-containing fluid into an aerosol to be breathed into the lungs. Recent data show that e-cigarettes are used by about one-fifth of U.S. high school students. Given that we have, in the Surgeon General's words, reached an epidemic of youth e-cigarette use, it is worth asking how a product within FDA jurisdiction became a serious threat to 3.6 million youth.

This Article reviews the law surrounding e-cigarettes and the history of FDA's attempts to regulate them. Administrative law doctrines instruct us that increased presidential control will rein in misbehaving agencies by allowing the people to vote out a president who improperly directs the administrative state. However, e-cigarettes present a potent counterexample. On multiple occasions, presidential control over FDA stymied essential tobacco regulations by increasing the influence of the tobacco industry over expert agency policymaking. Yet children harmed by these tobacco policies have no right to vote and little political clout with which to advocate for their interests. Ultimately, the emerging approach to regulating e-cigarettes stands in opposition to a looming historical context and a boiling epidemic of nicotine addiction. By painting the context of e-cigarettes in lush detail, drawing from history, law, medicine, and public health, this Article charts a path forward for e-cigarettes and other addicting products.

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A diverse class of alternative nicotine delivery systems (ANDS) has recently been developed that do not combust tobacco and are substantially less harmful than cigarettes. ANDS have the potential to disrupt the 120-year dominance of the cigarette . . . ANDS may provide a means to compete with, and even replace, combusted cigarette use, saving more lives more rapidly than previously possible.¹

—Professor David B. Abrams et al., 2018,
School of Global Public Health,
New York University

Initial hopes that e-cigarettes would be both a less toxic competitor to conventional cigarettes and a help to people who attempt to quit smoking cigarettes have not translated into real-world positive effects. Instead, e-cigarettes have simply become another class of tobacco products that are maintaining and expanding the tobacco epidemic.²

—Professor Stanton Glantz et al., 2018,
Center for Tobacco Control Research and Education,
University of California San Francisco

E-cigarettes are like watching a train wreck in slow motion.³

—Professor Allan M. Brandt, 2019,
Department of the History of Science and the
History of Medicine, Harvard University

¹ David B. Abrams, Allison M. Glasser, Jennifer L. Pearson, Andrea C. Villanti, Lauren K. Collins & Raymond S. Niaura, *Harm Minimization and Tobacco Control: Reframing Societal Views of Nicotine Use to Rapidly Save Lives*, 39 ANN. REV. PUB. HEALTH 193, 193 (2018).

² Stanton A. Glantz & David W. Bareham, *E-Cigarettes: Use, Effects on Smoking, Risks, and Policy Implications*, 39 ANN. REV. PUB. HEALTH 215, 227 (2018) (citation omitted).

³ Interview with Allan M. Brandt, Professor, Harvard University, in Cambridge, Mass. (Feb. 21, 2019).

INTRODUCTION

An e-cigarette is an electronic device that delivers heated nicotine-containing aerosol into the lungs.⁴ E-cigarettes are a tobacco product because they contain nicotine extracted from tobacco leaves.⁵ Nicotine—“among the most addictive substances used by humans”⁶—makes e-cigarettes exceptionally addictive. E-cigarettes were introduced into the United States in 2007⁷ and steadily gained popularity, particularly among children and teenagers. (**Figure 1**).



Figure 1: Various types of e-cigarettes.⁸

⁴ Jeffrey E. Gotts, Sven-Eric Jordt, Rob McConnell & Robert Tarran, *What Are the Respiratory Effects of E-Cigarettes?*, BMJ, Sept. 2019, at 1, 11. E-cigarettes generally work by vaporizing nicotine-containing fluid with heat. “Vaping” is a more expansive, but sometimes interchangeable, term for the inhalation of an aerosol from an electronic device; the aerosol generally contains nicotine or THC (the active ingredient in marijuana). Both e-cigarettes and vaping devices contain flavors, solvents, and/or other chemicals for proper functioning of the device. *Smoking & Tobacco Use: Frequently Asked Questions*, CTRS. FOR DISEASE CONTROL AND PREVENTION, https://www.cdc.gov/tobacco/basic_information/e-cigarettes/severe-lung-disease/need-to-know/index.html (last updated Dec. 1, 2020).

⁵ Gotts et al., *supra* note 4, at 1.

⁶ Nicopure Labs, LLC v. FDA, 944 F.3d 267, 270 (D.C. Cir. 2019).

⁷ Deeming Tobacco Products to be Subject to the Federal Food, Drug, and Cosmetic Act, 81 Fed. Reg. 28,974, 28,978 (May 10, 2016) (to be codified at 21 C.F.R. pts. 1100, 1140, & 1143) [hereinafter Deeming Rule].

⁸ *E-Cigarettes*, PIXABAY (Aug. 2, 2018), <https://pixabay.com/photos/ecigarette-juul-electronic-cigarette-3576177>.

E-cigarettes carried the hopes of researchers and advocates of reducing the heavy loss of life from traditional tobacco.⁹ But soon after they were brought to market, it became clear e-cigarettes were falling into the wrong hands. In 2018, the Surgeon General declared an e-cigarette epidemic among youth.¹⁰ He wrote:

I, Surgeon General of the United States Public Health Service, VADM Jerome Adams, am emphasizing the importance of protecting our children from a lifetime of nicotine addiction and associated health risks by immediately addressing the epidemic of youth e-cigarette use. The recent surge in e-cigarette use among youth, which has been fueled by new types of e-cigarettes that have recently entered the market, is a cause for great concern. *We must take action now to protect the health of our nation's young people.*¹¹

E-cigarette use by American teenagers increased 900% from 2011 to 2015.¹² It nearly doubled from 2017 to 2018,¹³ and teenagers now use e-cigarettes far more than they smoke.¹⁴ (Figure 2). Overall, tobacco use among youth was increasing until 2019—a finding FDA has called “startling.”¹⁵ Although e-cigarettes were framed as providing adults with a less harmful alternative to smoking, their per-capita use is far greater among youth.¹⁶

⁹ See Abrams et al., *supra* note 1, at 194.

¹⁰ See U.S. SURGEON GENERAL, 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>.

¹¹ *Id.* at 1 (emphasis in original).

¹² U.S. SURGEON GENERAL, E-CIGARETTE USE AMONG YOUTH AND YOUNG ADULTS: A REPORT OF THE SURGEON GENERAL, at vii (2016) [hereinafter 2016 REPORT], https://e-cigarettes.surgeongeneral.gov/documents/2016_sgr_full_report_non-508.pdf.

¹³ See Karen A. Cullen, Bridget K. Ambrose, Andrea S. Gentzke, Benjamin J. Apelberg, Ahmed Jamal & Brian A. King, *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. 1276, 1276 (2018). The apparent decrease in youth e-cigarette use between 2015 and 2017 was likely due to the failure to count Juul users in national data surveillance; Juul was introduced in 2015 and within two years dominated the market. See Jidong Huang, Zongshuan Duan, Julian Kwok, Steven Binns, Lisa E. Vera, Yoonsang Kim, Glen Szczypka & Sherry L. Emery, *Vaping vs. JUULing: How the Extraordinary Growth and Marketing of JUUL Transformed the U.S. Retail E-Cigarette Market*, 28 TOBACCO CONTROL 146, 150 (2019).

¹⁴ See Angelica LaVito, *Teen E-Cigarette Use Surged 75 Percent in the Past Year, Threatening Booming U.S. Market*, CNBC (Sept. 21, 2018, 7:11 PM), <https://www.cnbc.com/2018/09/21/teen-e-cigarette-use-is-surging-threatening-juul-and-others.html>.

¹⁵ See 2018 NYTS Data: A Startling Rise in Youth E-Cigarette Use, U.S. FOOD AND DRUG ADMIN. (Feb. 6, 2019), <https://www.fda.gov/tobacco-products/youth-and-tobacco/2018-nyts-data-startling-rise-youth-e-cigarette-use#references>.

¹⁶ In 2019, 27.5% of high-school students used e-cigarettes compared with 3.2% of adults. Brian A. King, Christopher M. Jones, Grant T. Baldwin & Peter A. Briss, *The EVALI and Youth Vaping Epidemics—Implications for Public Health*, 382 NEW ENG. J. MED. 689, 690 (2020).

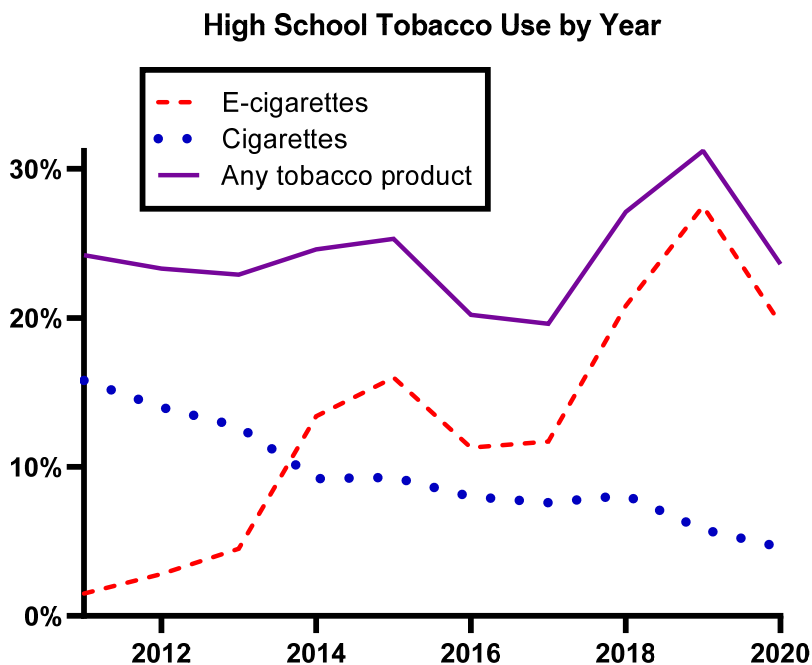


Figure 2: High school tobacco use by year, 2011–2019. Graph indicates the percentage of high schoolers who said in a survey they used a product at least once in the past 30 days.¹⁷

¹⁷ Past 30-day use is a useful metric that predicts future daily use and that offers earlier insight into an epidemic. See Lauren M. Dutra & Stanton A. Glantz, *Thirty-Day Smoking in Adolescence is a Strong Predictor of Smoking in Young Adulthood*, 109 PREVENTIVE MED. 17, 17, 19–20 (2018). Data is drawn from the National Youth Tobacco Survey. See Andrea S. Gentzke, Teresa W. Wang, Ahmed Jamal, Eunice Park-Lee, Chunfeng Ren, Karen A. Cullen & Linda Neff, *Tobacco Product Use Among Middle and High School Students—United States, 2020*, 69 MORBIDITY & MORTALITY WKLY. REP. 1881, 1884 (2020); Karen A. Cullen, *E-Cigarette Use Among Youth in the United States, 2019*, 322 JAMA 2095 (Supp. 2019); Tushar Singh, René A. Arrazola, Catherine G. Corey, Corinne G. Husten, Linda J. Neff, David M. Homa & Brian A. King, *Tobacco Use Among Middle and High School Students—United States, 2011–2015*, 65 MORBIDITY & MORTALITY WKLY. REP. 361, 363 (2016); René A. Arrazola, Tushar Singh, Catherine G. Corey, Corinne G. Husten, Linda J. Neff, Benjamin J. Apelberg, Rebecca E. Bunnell, Conrad J. Choiniere, Brian A. King, Shanna Cox, Tim McAfee & Ralph S. Caraballo, *Tobacco Use Among Middle and High School Students—United States, 2011–2014*, 64 MORBIDITY & MORTALITY WKLY. REP. 381, 382–83 (2015); René A. Arrazola, Linda J. Neff, Sara M. Kennedy, Enver Holder-Hayes & Christopher D. Jones, *Tobacco Use Among Middle and High School Students—United States, 2013*, 63 MORBIDITY & MORTALITY WKLY. REP. 1021, 1022–23 (2014); René A. Arrazola, Shanta R. Dube & Brian A. King, *Tobacco Product Use Among Middle and High School Students—United States, 2011 and 2012*, 62 MORBIDITY & MORTALITY WKLY. REP. 893, 895 (2013).

Much of the rise in e-cigarette use is driven by a particular e-cigarette brand called Juul. Juul e-cigarette fluid contains high levels of nicotine in a “salt” form, allowing fast absorption that mimics the biological effects of a combustible cigarette.¹⁸ Juul saw sales climb 769% during 2017 and, as of 2018, controlled 60% of the American e-cigarette market.¹⁹ Use of Juul is 16 times more frequent among youth 15–17 years of age compared with adults 25–34 years of age.²⁰

The surging use of e-cigarettes is quite surprising given the legal landscape over the past ten years, in which tobacco products came under increasing regulatory authority. The Family Smoking Prevention and Tobacco Control Act²¹ of 2009 was the culmination of a decade-long legal battle over the future of tobacco. The U.S. Food and Drug Administration (FDA) had been dealt a severe blow in 2000 when its assertion of jurisdiction over cigarettes as a drug and a device was struck down by the Supreme Court.²² One decade later, in 2009, FDA finally by statute acquired the authority to regulate tobacco products that were leading to hundreds of thousands of American deaths each year.²³ However, yet another court decision delayed FDA jurisdiction over e-cigarettes until 2016.²⁴ To this day, FDA has not reviewed any e-cigarette products sold in the United States—seemingly in contradiction with statutory requirements.²⁵

Given the e-cigarette epidemic among youth, one must ask whether the new regulatory regime surrounding tobacco products has failed. E-cigarettes offer tangible benefits to some Americans by providing an arguably less harmful substitute for combustible cigarettes; however, their use has become rampant among youth, leading to issues of intergenerational equity—differential harms and benefits to different generations. E-cigarettes, then, are a double-edged sword: they can benefit people who smoke as a harm reduction device, but their svelte appearance and aggressive

¹⁸ Huang et al., *supra* note 13, at 146.

¹⁹ LaVito, *supra* note 14. Although Juul’s market share has dropped, likely due to public criticism, it remains at a formidable 57% (as of January 2020). See Angelica LaVito, *Juul Bulks Up Its Science Staff as FDA Vaping Deadline Nears*, L.A. TIMES (Feb. 5, 2020, 1:36 PM), <https://www.latimes.com/business/story/2020-02-05/juul-science-fda-vaping>.

²⁰ Donna M. Vallone, Morgane Bennett, Haijun Xiao, Lindsay Pitzer & Elizabeth C. Hair, *Prevalence and Correlates of JUUL Use Among a National Sample of Youth and Young Adults*, 28 TOBACCO CONTROL 603, 607–08 (2018).

²¹ Pub. L. No. 111-31, 123 Stat. 1776 (2009) (codified as amended in scattered sections of 15 U.S.C. and 21 U.S.C.).

²² *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 126 (2000).

²³ See *Smoking & Tobacco Use: Fast Facts*, CTRS. FOR DISEASE CONTROL & PREVENTION, https://www.cdc.gov/tobacco/data_statistics/fact_sheets/fast_facts/index.htm (last updated May 14, 2021).

²⁴ See *Sottera, Inc. v. FDA*, 627 F.3d 891, 899 (D.C. Cir. 2010); see also *infra* Section I.A.1.

²⁵ See *infra* Section I.B.3.

marketing can lead to the addiction of new users, including children. Similar double-edged sword technologies, which have at times wrought severe damage on society, include opioids and certain medical devices.²⁶

As debates surrounding e-cigarettes continue,²⁷ many facts and important contexts have been omitted or forgotten. This paper will begin by examining the current status of e-cigarette regulation. It will then discuss contextual features of the epidemic, drawing from law, history, and the sciences, to build a holistic perspective on how a new technology like e-cigarettes may affect society. Finally, it will offer policy lessons for regulating e-cigarettes in a way that protects younger generations while allowing access for people who smoke.

E-cigarettes pose a troubling truth for public health agencies, and for administrative law more generally. When viewed in conjunction with concurrent public health crises, including opioids and COVID-19, e-cigarettes suggest that public health regulation is failing to protect the public. Regulations and the agencies that produce them are only as effective as situational constraints allow. Situational forces opposing agency action are at their zenith when agencies attempt to regulate products that are both “borderline” and profitable. That is, e-cigarettes exist on a jurisdictional dividing line and are promoted by powerful corporate interests. As a result, FDA regulation of e-cigarettes was obstructed at crucial moments by courts, the White House, Congress, and politics. This case study of e-cigarettes offers a test of theoretical administrative law principles such as presidential control over agency decision-making, the need for increased agency accountability, and the role of judicial review over agency action.

All three branches of government would do well to facilitate expert-driven regulations of health products to harness their benefits while averting mass harms. Congress can write statutes that delegate broader and more immediate authority. The White House can minimize political influence over expert agency decisions. And courts, rather than adopt formalistic interpretations of statutes, should recognize there is sound precedent in deferring to practical and reasonable uses of agency authority.²⁸ As the current technological age rapidly innovates new products within

²⁶ See, e.g., Andrew Kolodny, David T. Courtwright, Catherine S. Hwang, Peter Kreiner, John L. Eadie, Thomas W. Clark & G. Caleb Alexander, *The Prescription Opioid and Heroin Crisis: A Public Health Approach to an Epidemic of Addiction*, 36 ANN. REV. PUB. HEALTH 559, 560–61 (2015).

²⁷ See, e.g., Lawrence W. Green, Jonathan E. Fielding & Ross C. Brownson, *The Debate About Electronic Cigarettes: Harm Minimization or the Precautionary Principle*, 39 ANN. REV. PUB. HEALTH 189, 189 (2018) (“The two sides of this argument have produced a global divide on policy strategies.”).

²⁸ *Chevron U.S.A., Inc. v. Nat. Res. Def. Council, Inc.*, 467 U.S. 837, 866 (1984); *United States v. Article of Drug Bacto-Unidisk*, 394 U.S. 784, 791–92, 798 (1969) (holding that the Supreme Court must defer to (1) the agency’s medical expertise in construing a borderline product as a drug, and (2) Congress’s “overriding purpose to protect the public health”).

jurisdictional gray areas, it should not take a new statute, court review of this statute, rulemaking to obtain authority, litigation over this rulemaking, and the dodging of political landmines to create safeguards. Regulatory safeguards are essential to all health-related products,²⁹ and regulatory authority reasonably exercised should be swiftly upheld and encouraged.

Part I of this paper will review the current status of e-cigarette regulations. Part II will add context that is integral to proper regulation of e-cigarettes. Part III will offer worrisome observations about the regulation of addicting products. Part IV will offer solutions.

I. CURRENT STATUS OF E-CIGARETTE REGULATION

To this day, e-cigarettes exist largely in a regulatory vacuum. FDA has asserted jurisdiction over e-cigarettes under the Family Smoking Prevention and Tobacco Control Act³⁰ of 2009 (hereinafter “Tobacco Control Act” or “TCA”). Unfortunately, the statute was not designed for swift e-cigarette regulation, and FDA has taken relatively few regulatory steps under its new authority. Further, FDA postponed compliance dates for e-cigarette premarket review to 2022, a decision which, though recently vacated in federal court, has led to significant delays in substantive regulation. Currently, e-cigarette manufacturers enjoy a regulatory hole, privileging them over other tobacco products (e.g., cigarettes) and nicotine-replacement therapy (e.g., the patch).

This Part will offer background on the TCA, its substantive provisions, and their application to e-cigarettes. It will then discuss the jurisdictional issues with the regulation of e-cigarettes. It will conclude by laying out the steps FDA has taken with regard to e-cigarettes and the responses, including litigation, from industry and public health officials. This paper focuses on federal law; however, state and local law are fertile ground for tobacco regulation.

A. *The Statute*

The TCA was inspired, according to its Preamble, by the 400,000 tobacco-related deaths in the United States each year, the approximately 8,600,000 Americans with chronic tobacco-related diseases, and a projected savings of \$75 trillion in healthcare costs if youth tobacco use is reduced by 50%.³¹ The TCA instructs FDA to establish a new Center for Tobacco Products dedicated to tobacco regulation.³²

²⁹ For examples of safeguards, see *infra* Part IV.

³⁰ Pub. L. No. 111-31, 123 Stat. 1776 (2009) (codified in scattered sections of 15 U.S.C. and 21 U.S.C.).

³¹ See *id.* §§ 2(13)–(14).

³² Federal Food, Drug, and Cosmetic Act (FDCA) of 1938 § 901(e), 21 U.S.C. § 387a(e) (2018).

1. *Jurisdiction and the Deeming Provision*

The TCA grants FDA authority over tobacco products,³³ but one sentence later states the Act applies only to certain listed products,³⁴ not including e-cigarettes, until FDA “deems” other tobacco products to be covered by the statute.³⁵ A “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.”³⁶ At the time of the Act’s passing, it was unknown that e-cigarettes would become a dominant player in the tobacco marketplace, but the statute left open the possibility of FDA regulation over additional tobacco products. Unfortunately, this regulatory design allowed new tobacco products to enter the market free of FDA regulation until FDA issued a rule deeming those products within the TCA. And while FDA attempted to assert jurisdiction over e-cigarettes under its drug and device authorities, the D.C. Circuit rejected this idea.³⁷

In 2016, seven years after the TCA, FDA issued the so-called Deeming Rule, which declared authority over “all other products meeting the definition of *tobacco product*,”³⁸ including e-cigarettes. Continued FDA jurisdiction over e-cigarettes depends on the validity, constitutional and otherwise, of the TCA *and* the Deeming Rule.

2. *Regulatory Framework and the “Public Health” Standard*

The TCA provides FDA a number of powers over tobacco products, including the approval of new tobacco products,³⁹ approval of modified-risk (i.e., reduced risk) tobacco products,⁴⁰ the creation of tobacco product standards,⁴¹ issuance of sales, distribution, and advertising restrictions,⁴² collection of information about

³³ FDCA § 901(a), 21 U.S.C. § 387a(a).

³⁴ These products are “cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco.” FDCA § 901(b), 21 U.S.C. § 387a(b).

³⁵ *Id.*

³⁶ FDCA § 201(rr)(1), 21 U.S.C. § 321(rr)(1).

³⁷ *See Sottera, Inc. v. FDA*, 627 F.3d 891, 899 (D.C. Cir. 2010).

³⁸ Tobacco Products Subject to FDA Authority, 21 C.F.R. § 1100.1 (2016) (emphasis in original); Deeming Rule, *supra* note 7, at 29,056. The rule was later clarified to exclude products intended to be used to treat or prevent disease, such as nicotine replacement therapy (e.g., the patch), which are regulated under other provisions of the FDCA, rather than under the TCA. *See* Tobacco Products Subject to FDA Authority, 21 C.F.R. § 1100.5 (2017); Tobacco Products Subject to FDA Authority, 82 Fed. Reg. 2217 (Jan. 9, 2017) (to be codified at 21 C.F.R. pt. 1100).

³⁹ FDCA § 910, 21 U.S.C. § 387j.

⁴⁰ FDCA § 911, 21 U.S.C. § 387k.

⁴¹ FDCA § 907, 21 U.S.C. § 387g.

⁴² FDCA § 906, 21 U.S.C. § 387f.

tobacco products on the market,⁴³ and enforcement powers.⁴⁴ The TCA also contains other substantive provisions, such as banning most flavored cigarettes.⁴⁵

While most products regulated by FDA are intended to benefit societal health, and therefore can be evaluated for safety and effectiveness, tobacco products bring primarily risks, are always unsafe, and are often ineffective for any therapeutic purpose.⁴⁶ Therefore, the writers of the TCA faced the challenge of selecting a legal standard. The final product is the “public health” standard, which guides FDA action based on what is “appropriate for the protection of the public health.”⁴⁷ When assessing whether an action is appropriate to protect the public health, FDA generally must consider the “risks and benefits to the population as a whole, including users and nonusers of the tobacco product”⁴⁸—in the case of e-cigarettes, largely adults who want to quit cigarettes, and children who do not use tobacco.

3. *Premarket Review*

As for drugs, there are several pathways for new tobacco products to enter the market. FDA may approve pre-market tobacco applications (PMTAs) when appropriate for the protection of public health.⁴⁹ Tobacco products that are advertised to have a lower risk may be approved through the modified-risk tobacco product (MRTP) pathway if (1) approval is appropriate for public health, (2) the product will “significantly reduce harm and the risk of tobacco-related disease to individual tobacco users,” and (3) labeling will allow the public to understand the significance of the lower risk profile in context of total health and tobacco use generally.⁵⁰ At first glance, it appears no new type of tobacco product could be “appropriate for the protection of the public health” unless it carries a reduced risk.⁵¹ Thus, the PMTA pathway may seem superfluous. However, the PMTA pathway has become dominant for new tobacco products due to its lower evidentiary burden; only two types of modified-risk products have passed FDA review—Swedish Match smokeless snus

⁴³ FDCA § 904, 21 U.S.C. § 387d.

⁴⁴ FDCA §§ 902–03, 908–09, 21 U.S.C. §§ 387b–c, 387h–i.

⁴⁵ See FDCA § 907(a)(1)(A), 21 U.S.C. § 387g(a)(1)(A).

⁴⁶ See INST. OF MED., SCIENTIFIC STANDARDS FOR STUDIES ON MODIFIED RISK TOBACCO PRODUCTS, at x (2012) (“Regulating tobacco products creates unique challenges. Unlike most products regulated by the FDA, tobacco is inherently hazardous and offers primarily risks rather than any significant physiological benefit to the user’s health.”).

⁴⁷ *E.g.*, FDCA § 906(d)(1), 21 U.S.C. § 387f(d)(1); FDCA § 907(a)(3)(A), 21 U.S.C. § 387g(a)(3)(A); see also INST. OF MED., *supra* note 46, at 38.

⁴⁸ *E.g.*, FDCA § 906(d)(1), 21 U.S.C. § 387f(d)(1) (2018)).

⁴⁹ FDCA § 910(c)(2), 21 U.S.C. § 387j(c)(2).

⁵⁰ FDCA § 911(g)(1), 21 U.S.C. § 387k(g)(1); FDCA § 911(h)(1), 21 U.S.C. § 387k(h)(1).

⁵¹ See PETER BARTON HUTT, RICHARD A. MERRILL & LEWIS A. GROSSMAN, FOOD AND DRUG LAW 1358 (4th ed., 2014).

and the Philip Morris new “heat-not-burn” electronic IQOS system.⁵² These two approvals suggest FDA may place high value on the lack of combustion, a feature e-cigarettes share.⁵³

4. *Funding*

The TCA provided FDA authority to collect user fees from tobacco manufacturers to establish its Center for Tobacco Products (CTP); the total is established by the statute and increased from \$85 million in 2009 to \$712 million in 2019 and beyond.⁵⁴ FDA may not use other funds to support its tobacco activities.⁵⁵

Given the lack of substantive regulatory actions taken by FDA toward e-cigarettes, it is worthwhile to consider whether FDA has lacked sufficient resources. While \$712 million seems like a large sum, CTP exceeded its budget in 2019, nearly exhausted its entire budget in 2018, and exceeded its budget in 2017 by over \$150 million.⁵⁶ CTP has openly expressed that limited resources constrain its tobacco

⁵² See *Modified Risk Orders*, U.S. FOOD & DRUG ADMIN. (July 21, 2020), <https://www.fda.gov/tobacco-products/advertising-and-promotion/mrtp-application-actions-orders-denials-and-responses>; *FDA Grants First-Ever Modified Risk Orders to Eight Smokeless Tobacco Products*, FDA (Oct. 22, 2019), <https://www.fda.gov/news-events/press-announcements/fda-grants-first-ever-modified-risk-orders-eight-smokeless-tobacco-products>. An alternative pathway for marketing tobacco products, that of “substantial equivalence,” will likely be irrelevant for e-cigarettes. A tobacco manufacturer can bypass the approval process and file a report with FDA 90 days before entering the market if the manufacturer determines that its new product is substantially equivalent to a product marketed prior to February 15, 2007—or substantially equivalent to another substantially equivalent product. FDCA § 905(j)(1), 21 U.S.C. § 387e(j)(1). There is only one known e-cigarette product that could serve as a predicate. Deeming Rule, *supra* note 7, at 28,991. For traditional tobacco products, however, substantial equivalence has become the dominant approval pathway, which has subjected FDA to criticism for insufficient evaluation of new products. See, e.g., Desmond Jenson, Joelle Lester & Micah L. Berman, *FDA’s Misplaced Priorities: Premarket Review Under the Family Smoking Prevention and Tobacco Control Act*, 25 TOBACCO CONTROL 246, 246–47 (2016).

⁵³ However, the absence of combustion is insufficient to establish safety. See *infra* Section II.A.2.

⁵⁴ FDCA §§ 919(a)–(b), 21 U.S.C. § 387s(a)–(b).

⁵⁵ FDCA § 919(c)(2)(B)(i), 21 U.S.C. § 387s(c)(2)(B)(i).

⁵⁶ See U.S. FOOD & DRUG ADMIN., FISCAL YEAR 2021: JUSTIFICATION OF ESTIMATES FOR APPROPRIATIONS COMMITTEES 20 (2020), <https://www.fda.gov/media/135078/download>; U.S. FOOD & DRUG ADMIN., FISCAL YEAR 2020: JUSTIFICATION OF ESTIMATES FOR APPROPRIATIONS COMMITTEES 16, 18 (2019), <https://www.fda.gov/media/121408/download>; U.S. FOOD & DRUG ADMIN., FISCAL YEAR 2019: JUSTIFICATION OF ESTIMATES FOR APPROPRIATIONS COMMITTEES 16, 18 (2018), <https://www.fda.gov/media/112611/download>. As of 2019, CTP possessed a “carryover” from prior years totaling around \$240 million. See U.S. FOOD & DRUG ADMIN., REPORT TO THE HOUSE COMMITTEE ON APPROPRIATIONS: TOBACCO PRODUCT USER FEES 4 (2019), <https://www.fda.gov/media/131981/download>. However, funding constraints will remain a pressing issue for the Center given it faces millions of submitted tobacco product applications. See Mitch Zeller, *Perspective: FDA’s Progress on Review of Tobacco Product Applications*

enforcement.⁵⁷ Further, CTP is arguably understaffed relative to other FDA centers. CTP comprises 12% of FDA's budget, but only contains 5% of the agency's full-time employees (880 total employees as of 2018),⁵⁸ suggesting the existence of either large non-human-resource expenses or a high premium on hiring tobacco experts. A significant number of FDA's tobacco regulators have left for the e-cigarette industry.⁵⁹ If nothing else, funding limitations may be one barrier to the recruitment and retention of tobacco experts.

5. *Severability and Challenges to the TCA*

Courts have seen many challenges to the TCA, which are beyond the scope of this Article.⁶⁰ Most are directed at particular provisions, which are therefore unlikely to invalidate the TCA in toto given a severability clause,⁶¹ and the lack of any apparent congressional intent that the provisions of the Act may only stand together.⁶²

B. *FDA Regulation of E-Cigarettes*

FDA had attempted to regulate e-cigarettes as early as 2008 under its drug and device authorities. However, several court rulings determined that FDA could not substantively regulate e-cigarettes until it deemed them a tobacco product within the scope of the TCA. In accordance with these rulings, FDA's 2016 "Deeming Rule" declared the agency's authority under the TCA over all products meeting the

Submitted by the Sept. 9, 2020 Deadline (Feb. 16, 2021), <https://www.fda.gov/tobacco-products/ctp-newsroom/perspective-fdas-progress-review-tobacco-product-applications-submitted-sept-9-2020-deadline>.

⁵⁷ See U.S. FOOD & DRUG ADMIN., ENFORCEMENT PRIORITIES FOR ELECTRONIC NICOTINE DELIVERY SYSTEMS (ENDS) AND OTHER DEEMED PRODUCTS ON THE MARKET WITHOUT PREMARKET AUTHORIZATION 31 (Apr. 2020), <https://www.fda.gov/media/133880/download>.

⁵⁸ See *Fact Sheet: FDA at a Glance*, U.S. FOOD & DRUG ADMIN. (June 14, 2019), <https://www.fda.gov/about-fda/fda-basics/fact-sheet-fda-glance>; U.S. FOOD & DRUG ADMIN., DETAIL OF FULL-TIME EQUIVALENT EMPLOYMENT (FTE) (2018), <https://www.fda.gov/media/106372/download>.

⁵⁹ See LaVito, *supra* note 19.

⁶⁰ See *Case Summaries: Lawsuits Related to the 2016 Deeming Rule*, PUB. HEALTH LAW CTR., <https://www.publichealthlawcenter.org/content/tobacco-control-act-cases> (last visited July 29, 2021).

⁶¹ See Family Smoking Prevention and Tobacco Control Act, H.R. 1256, 111th Cong. § 5 (2009).

⁶² See, e.g., *Nat'l Fed. of Indep. Bus. v. Sebelius*, 567 U.S. 519, 586–87 (2012) (quoting *Champlin Ref. Co. v. Corp. Comm'n of Okla.*, 286 U.S. 210, 234 (1932)) ("The question here is whether Congress would have wanted the rest of the Act to stand . . . Unless it is 'evident' that the answer is no, we must leave the rest of the Act intact."); *INS v. Chadha*, 462 U.S. 919, 934 (1983) (quoting *Champlin Ref. Co.*, 286 U.S. at 234) ("A provision is further presumed severable if what remains after severance 'is fully operative as a law.'").

statutory definition of “tobacco product,” including e-cigarettes.⁶³ However, FDA has voluntarily postponed enforcement of premarket review requirements on multiple occasions; therefore, e-cigarette products on the market are not approved as appropriate for the protection of public health.

1. *Early FDA Attempts to Regulate E-Cigarettes*

In 2008, prior to the Deeming Rule and the TCA, FDA had attempted to regulate e-cigarettes as drug-device combinations under the Federal Food, Drug, and Cosmetic Act (FDCA).⁶⁴ However, the D.C. Circuit extended *FDA v. Brown & Williamson Tobacco Corp.*,⁶⁵ holding that FDA lacks jurisdiction not just over cigarettes, but over all recreational tobacco products.⁶⁶ It is particularly surprising that the Court extended the holding of *Brown & Williamson* given several key differences between cigarettes and e-cigarettes.⁶⁷

The D.C. Circuit also reasoned that Congress intended tobacco products to be regulated under the TCA,⁶⁸ which was passed mid-litigation. Formally speaking, the decision prohibited FDA jurisdiction over e-cigarettes under one portion of the FDCA in part based on a newly enacted Title of the same Act. While this seems like a minor difference, the biggest practical effect was that e-cigarette jurisdiction under the TCA was not automatic, but required time consuming notice-and-comment rulemaking by a fledgling FDA tobacco center.⁶⁹

2. *The Deeming Rule*

Finally, in 2016, after publication of the Deeming Rule, e-cigarette manufacturers were subjected to a similar statutory burden as other tobacco companies.⁷⁰ In

⁶³ Tobacco Products Subject to FDA Authority, 21 C.F.R. § 1100.1 (2016); Deeming Rule, *supra* note 7, at 29,056.

⁶⁴ See Eric A. Feldman, *Layers of Law: The Case of E-Cigarettes*, 10 FIU L. REV. 111, 123–24 (2014).

⁶⁵ 529 U.S. 120 (2000).

⁶⁶ *Sottera, Inc. v. FDA*, 627 F.3d 891, 895, 898–99 (D.C. Cir. 2010).

⁶⁷ Foremost in the reasoning of *Brown & Williamson* is that cigarettes have no safe intended use, and therefore FDA could not assert jurisdiction without banning them. See *Brown & Williamson*, 529 U.S. at 142. However, e-cigarettes are frequently promoted as cessation devices and thus are conceivably within the existing regulatory authority of FDA. Other factors that differ from *Brown & William’s* analysis are (1) FDA had not renounced its own jurisdiction over e-cigarettes, *id.* at 151–52; (2) prior congressional statutes had not spoken to jurisdiction over e-cigarettes as they had for cigarettes, *id.* at 153–55; and (3) e-cigarettes did not present the same economic significance to invoke the major question doctrine, which would disfavor an implicit delegation of tobacco authority, *id.* at 159–60. Therefore, the fundamental arguments from *Brown & Williamson* that led the Supreme Court to ignore the plain meaning of the Federal Food, Drug, & Cosmetic Act are absent for e-cigarettes.

⁶⁸ *Sottera*, 627 F.3d at 897.

⁶⁹ See *supra* Section I.A.1.

⁷⁰ See Deeming Rule, *supra* note 7, at 28,974.

addition, the Deeming Rule, wielding FDA's authority under TCA Section 906(d) to create new restrictions on sales, distribution, and advertising,⁷¹ imposed several new requirements, including a minimum purchase age of 18, a photo identification requirement,⁷² and restrictions on e-cigarette vending machines.⁷³ Importantly, the rule also required a warning label on e-cigarette packaging and advertisements stating, "WARNING: This product contains nicotine. Nicotine is an addictive chemical."⁷⁴ Finally, it laid out a three-year timetable for premarket review.⁷⁵

The Deeming Rule, therefore, granted FDA full statutory authority over e-cigarettes while imposing substantive health-promoting regulations upon manufacturers and retailers. It represented a culmination of seven years of work at FDA, from the signing of the TCA in 2009 to the rule's finalization in 2016.

While the Deeming Rule was an essential step toward regulating e-cigarettes, it did not offer much to change the course of rising youth e-cigarette use. It did not actualize premarket review, instead laying out a timetable.⁷⁶ The draft Deeming Rule did contain a ban on flavored e-cigarettes given their appeal to children, but the flavor ban was removed before issuance; this change became the topic of an L.A. Times exposé on e-cigarette industry lobbying.⁷⁷ After e-cigarettes enjoyed seven years of the free market, the Deeming Rule offered a timid beginning to regulation.

Nonetheless, e-cigarette manufacturers responded quickly to the Deeming Rule with litigation,⁷⁸ which, if successful, threatens to remove e-cigarettes from the scope of the TCA or invalidate portions of the TCA, at least as applied to e-cigarettes. Table 1 below offers a review of current and past litigation surrounding the Deeming Rule, organized by type of claim. The breadth of claims against the Deeming Rule suggests the economic importance to e-cigarette manufacturers of defeating

⁷¹ Federal Food, Drug, and Cosmetic Act (FDCA) of 1938 § 906(d), 21 U.S.C. § 387f(d) (2018).

⁷² U.S. FOOD & DRUG ADMIN., FDA DEEMS CERTAIN TOBACCO PRODUCTS SUBJECT TO FDA AUTHORITY, SALES AND DISTRIBUTION RESTRICTIONS, AND HEALTH WARNING REQUIREMENTS FOR PACKAGES AND ADVERTISEMENTS (REVISED) 1, 19 (Apr. 2020), <https://www.fda.gov/media/97664/download>; *see also* Cigarettes, Smokeless Tobacco, and Covered Tobacco Products, 21 C.F.R. §§ 1140.14(a)–(b) (2016); Deeming Rule, *supra* note 7, at 29,103.

⁷³ 21 C.F.R. § 1140.14(c); Deeming Rule, *supra* note 7, at 29,057.

⁷⁴ Deeming Rule, *supra* note 7, at 28,988.

⁷⁵ *Id.* at 29,011.

⁷⁶ *See infra* Section II.A.3.

⁷⁷ *See infra* Section II.B.5; 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>.

⁷⁸ *See Current Status of Deeming Litigation*, PUB. HEALTH LAW CTR. (2019), <https://publichealthlawcenter.org/topics/tobacco-control/fda-tobacco-action-center/current-status-deeming-litigation>.

the rule. Predominant are challenges under the First Amendment and the Administrative Procedure Act.

Type of Challenge	Number
First Amendment: Free-sample prohibition, modified-risk statements, warning labels, premarket review are unconstitutional.	12
APA: Premarket review is arbitrary and capricious or unlawful.	6
APA: Regulatory impact analysis/cost-benefit analysis were unlawful.	6
RFA: Regulatory flexibility analysis was unlawful or did not consider less costly alternatives.	4
APA: FDA interpretation of “tobacco product” is unlawful.	4
APA: Other arbitrary and capricious claims.	3
APA: Warning labels are arbitrary and capricious.	2
Fifth Amendment: Warning labels, prohibition of modified-risk statements are unlawful takings.	2
Appointments Clause: Employee on federal register notice is neither principal nor inferior officer.	2
APA: User fees exceed statutory authority.	1
TCA/APA: FDA did not make required statutory findings before requiring warning labels.	1
Fourteenth Amendment: Treating e-cigarettes similarly to cigarettes violates the Equal Protection Clause.	1
Fifth Amendment: Premarket review violates the Due Process Clause.	1
Fifth Amendment: Imposition of user fees on cigar manufacturers but not e-cigarette manufacturers violates the Due Process Clause.	1
Tenth Amendment: Removal of e-cigarettes from the market deprives states of sovereignty in reducing the healthcare costs of smoking.	1

Table 1: Claims against the Deeming Rule as of September 2019.⁷⁹ Abbreviations: APA = Administrative Procedure Act; RFA = Regulatory Flexibility Act; TCA = Tobacco Control Act.

⁷⁹ See *Lawsuits Challenging the FDA’s Deeming Rule* (2019), PUB. HEALTH LAW CTR. (Mar. 5, 2019), <https://www.publichealthlawcenter.org/resources/lawsuits-challenging-fda-deeming-rule>. The data in Table 1 covers known challenges to the Deeming Rule, including all relevant cases found on LexisNexis and Google with the search term “Deeming Rule,” as of September 2019.

The leading case exemplifying the claims in Table 1 is *Nicopure Labs, LLC v. FDA*,⁸⁰ in which an e-cigarette manufacturer and an e-cigarette industry group unsuccessfully challenged the Deeming Rule under various legal theories, three of which will be discussed here. Several conclusions upholding the rule were appealed, and a three-judge panel on the U.S. Court of Appeals for the District of Columbia Circuit unanimously affirmed with one of the most surprisingly favorable decisions for FDA perhaps in history.⁸¹

First, plaintiffs argued that FDA may not under the TCA regulate empty vaping devices sold without nicotine as “tobacco products.”⁸² However, the District of D.C. held FDA’s interpretation of the TCA reasonable under *Chevron* step two, declaring that empty vaping devices intended to be used with nicotine are reasonably considered tobacco products.⁸³ This claim was not appealed.

Second, plaintiffs contended that FDA’s subjection of e-cigarettes to regulation is arbitrary and capricious under the Administrative Procedure Act because it fails to account for the health benefits of e-cigarettes, and therefore undermines the purpose of the TCA to reduce smoking-related illness and death.⁸⁴ The D.C. Circuit disagreed, noting that the industry was essentially asking the Court to free e-cigarettes from a regulatory regime for public health reasons, when public health assessment is the very purpose of the regulatory regime.⁸⁵

Third, plaintiffs asserted that the restriction on selling and marketing modified-risk tobacco products (MRTPs) without approval infringes on free speech protected by the First Amendment.⁸⁶ On the contrary, the D.C. Circuit held that the MRTP review pathway does not regulate speech.⁸⁷ For this holding, the Court relied on *Whitaker v. Thompson*,⁸⁸ in which FDA refused to allow a supplement manufacturer to label its supplement with claims that it could mitigate the disease benign prostatic hyperplasia.⁸⁹ Under the FDCA, any article “intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease” is a drug.⁹⁰ The D.C. Circuit in *Whitaker* held that FDA was not regulating speech, but rather using

⁸⁰ 266 F. Supp. 3d 360 (D.D.C. 2017).

⁸¹ See *Nicopure Labs, LLC v. FDA*, 944 F.3d 267 (D.C. Cir. 2019).

⁸² *Nicopure*, 266 F. Supp. 3d at 380.

⁸³ *Id.* at 385–86.

⁸⁴ *Id.* at 396.

⁸⁵ *Nicopure*, 944 F.3d at 282–83.

⁸⁶ *Nicopure*, 266 F. Supp. 3d at 368–69.

⁸⁷ However, the Court conducted a *Central Hudson* test just in case. See *Nicopure*, 944 F.3d at 283–84.

⁸⁸ 353 F.3d 947 (D.C. Cir. 2004).

⁸⁹ *Id.* at 948–49.

⁹⁰ Federal Food, Drug, and Cosmetic Act (FDCA) of 1938 § 201(g)(1), 21 U.S.C. § 21(g)(1) (2018).

speech as evidence of product type.⁹¹ Because drugs must be approved as safe and effective, the product in *Whitaker* had to be removed from the market or the claim removed.⁹² Of course, this logic has the effect of limiting certain types of speech. However, our drug regulatory system would be peculiar indeed if manufacturers could advertise their products as drugs yet enjoy the lenient regulations of a dietary supplement. Such a product would be in blatant violation of drug regulations.

By the same token, in *Nicopure*, the D.C. Circuit held that speech can be used by FDA as evidence of the product category.⁹³ That is, should a manufacturer make a modified-risk claim, it is now selling a modified-risk product that requires approval through the modified-risk pathway.⁹⁴ Any burdened speech is thus associated with an illegal transaction and not protected by the First Amendment.⁹⁵

This result, in 2019, is quite important for FDA and is strikingly different from what other circuits have held. For example, the Sixth Circuit assessed the same MRTP provision of the TCA in *Discount Tobacco City & Lottery, Inc. v. United States*,⁹⁶ determining that “there is no cognizable First Amendment difference between a law that directly proscribes promotional speech and one that renders a product’s sale illegal based on promotional speech.”⁹⁷ The Court still upheld the MRTP requirements under *Central Hudson*, noting a historical “pattern of deception” in the marketing of “light” and reduced-risk cigarettes, and the substantial government interest in preventing such deception.⁹⁸ Still, the application of the First Amendment to regulatory categorization was worrisome.

And in 2012, the Second Circuit took the most critical view of FDA regulations touching speech in *United States v. Caronia*.⁹⁹ In this criminal appeal, pharmaceutical sales representative Alfred Caronia overturned his conviction for misbranding through off-label marketing of the central nervous system drug Xyrem (gamma-hydroxybutyrate).¹⁰⁰ Although FDA approved Xyrem for treating patients with narcolepsy, Caronia breached FDA rules by marketing the drug to physicians for a wide variety of other uses, including insomnia, restless leg syndrome, fibromyalgia, Parkinson’s disease, and chronic pain, as well as for youth under 16 for whom there was a mandatory Black Box warning.¹⁰¹ The Court first subjected the FDA

⁹¹ *Whitaker*, 353 F.3d at 953.

⁹² *Id.* at 949.

⁹³ *Nicopure Labs, LLC v. FDA*, 944 F.3d at 283 (D.C. Cir. 2019).

⁹⁴ *See id.* at 283–84.

⁹⁵ *Id.* at 284.

⁹⁶ 674 F.3d 509 (6th Cir. 2012).

⁹⁷ *Id.* at 534.

⁹⁸ *Id.* at 535–37.

⁹⁹ 703 F.3d 149 (2d Cir. 2012).

¹⁰⁰ *Id.* at 152, 155.

¹⁰¹ *Id.* at 155–57.

off-label rule to strict scrutiny and stated it was presumptively invalid, reasoning that the rule was content-based (it allowed “on-label” claims) and speaker-based (it applied only to salespeople—not to, say, academics).¹⁰² The Court emphasized the importance of protecting truthful content-based speech and, using the *Central Hudson* test, held that (1) FDA’s regulations inadequately furthered the purpose of promoting health because they restrict dissemination of truthful information germane to treatment decisions, and (2) FDA insufficiently considered alternatives.¹⁰³ The Court may have been influenced by the criminal nature of this case, which made FDA enforcement seem more like a regulation of speech.

In the context of *Discount Tobacco* and *Caronia*, *Nicopure* is a resounding victory for FDA. From a public health standpoint, FDA has strong arguments that liberating the use of modified-risk claims like “light” for tobacco products could have a detrimental effect on public health, as tobacco users frequently believe “light” products are safer even though they typically are just as harmful.¹⁰⁴ Some deference is also due to the regulatory regime Congress chose, and so applying constitutional scrutiny to a congressional statute regulating a product as dangerous and addicting as tobacco feels close to overextending the reach of an Article III court.¹⁰⁵ Indeed, the *Nicopure* court flatly acknowledged the obvious importance of a tobacco control regime; its first sentence of the opinion is “Nicotine is among the most addictive substances used by humans,” and in the same paragraph it emphasizes the important goals of Congress in passing the TCA.¹⁰⁶ *Nicopure* is a powerful opinion for its holding but also for its expressive force in the value of tobacco regulation.

In sum, litigants have brought an array of legal challenges to the Deeming Rule as well as the individual provisions of the TCA that the Deeming Rule imposed on

¹⁰² *Id.* at 164–65. Most conceivable marketing rules necessarily regulate by speaker and content. For example, consider a company that wants to market rubbing alcohol as effective for treating seizures. It is socially beneficial to prevent such marketing, even if we allow ordinary people to make the same claim, or that company to make a different but well-founded claim. Therefore, regulation of the claim that rubbing alcohol can treat seizures will necessarily be content- and speaker-based.

¹⁰³ *See id.* at 166–68 (quoting *Sorrell v. IMS Health Inc.*, 564 U.S. 552, 566 (2011)) (“[I]n the fields of medicine and public health, ‘where information can save lives,’ it only furthers the public interest to ensure that decisions about the use of prescription drugs, including off-label usage, are intelligent and well-informed.”).

¹⁰⁴ *See Disc. Tobacco City & Lottery, Inc. v. United States*, 674 F.3d 509, 534–36 (6th Cir. 2012) (quoting *United States v. Philip Morris USA, Inc.*, 449 F. Supp. 2d 1, 430 (D.D.C. 2006)) (“[F]or several decades, [the major tobacco manufacturers] have marketed and promoted their low tar brands as being less harmful than conventional cigarettes. That claim is false . . . [and b]y making these false claims, [the major tobacco manufacturers] have given smokers an acceptable alternative to quitting smoking, as well as an excuse for not quitting.”).

¹⁰⁵ *Cf. Janus v. AFSCME*, Council 31, 138 S. Ct. 2448, 2501–02 (2018) (Kagan, J., dissenting) (asserting the Supreme Court has turned the First Amendment into a “sword”).

¹⁰⁶ *See Nicopure Labs, LLC v. FDA*, 944 F.3d 267, 270–71 (D.C. Cir. 2019).

e-cigarette companies. Assuming the survival of *Chevron* deference, it is unlikely FDA's entire Deeming Rule will be invalidated in toto given that e-cigarette fluid generally contains tobacco extract, and therefore e-cigarettes and their component parts reasonably fall into the statutory definition of "tobacco product." However, rising judicial skepticism of *Chevron* and other forms of deference to administrative determinations suggests that the Deeming Rule may undergo more searching judicial review now or in the future.¹⁰⁷

3. Premarket Review

Although the Deeming Rule is now in full effect (subject to litigation), most e-cigarette products entered the market before FDA had authority over them. FDA has not brought e-cigarettes into compliance with the statute.¹⁰⁸ Therefore, most e-cigarettes continue to enjoy privileged regulatory status and FDA has generally not enforced premarket review requirements established by the Tobacco Control Act.¹⁰⁹ Tobacco experts Desmond Jenson, Joelle Lester, and Micah Berman are openly critical, arguing that FDA's failure to timely implement premarket review of tobacco products "undermine[s] its ability to protect the public."¹¹⁰ The course of premarket review is worth spelling out in more detail.

In 2016, the newly promulgated Deeming Rule declared that FDA would allow two years for e-cigarette companies to submit premarket tobacco applications for existing products, and would allow products associated with a submitted application to remain on the market for an additional year during review.¹¹¹ Under this plan, by August 8, 2019, only e-cigarettes with an affirmative marketing order by FDA were to be allowed on the market.¹¹² Because unapproved e-cigarettes are still on the market, it is clear the Deeming Rule plan never came to fruition. Instead, in 2017, sans notice-and-comment rulemaking,¹¹³ FDA asserted its enforcement discretion through guidance to extend the compliance deadline for new e-cigarette pre-

¹⁰⁷ See Gillian E. Metzger, *1930s Redux: The Administrative State Under Siege*, 131 HARV. L. REV. 1, 24 (2017).

¹⁰⁸ See U.S. FOOD & DRUG ADMIN., EXTENSION OF CERTAIN TOBACCO PRODUCT COMPLIANCE DEADLINES RELATED TO THE FINAL DEEMING RULE (Nov. 2017), <https://wayback.archiveit.org/7993/20180124142324/https://www.fda.gov/downloads/TobaccoProducts/Labeling/RulesRegulationsGuidance/UCM557716.pdf>.

¹⁰⁹ See *id.*; Federal Food, Drug, and Cosmetic Act (FDCA) of 1938 § 910(c), 21 U.S.C. § 387j(c) (2018); FDCA § 911(g)(1), 21 U.S.C. § 387k(g)(1).

¹¹⁰ Jenson et al., *supra* note 52, at 251.

¹¹¹ Deeming Rule, *supra* note 7, at 29,045; *Extensions & An Epidemic: The FDA's Gatekeeping Authority for E-Cigarettes*, PUB. HEALTH LAW CTR. 5 (Feb. 2019), <https://www.publichealthlawcenter.org/sites/default/files/resources/FDA-Gatekeeping-Authority-ECigarettes-2019.pdf> (explanatory graphics).

¹¹² See Deeming Rule, *supra* note 7, at 29,045.

¹¹³ *Am. Acad. of Pediatrics v. FDA*, 379 F. Supp. 3d 461, 472 (D. Md. 2019).

market applications to August 8, 2022, and announced that e-cigarettes with a submitted application may remain on the market indefinitely until review.¹¹⁴ It is unclear why FDA changed course, but it likely had to do with the 2017 appointment of Dr. Scott Gottlieb as FDA commissioner,¹¹⁵ and the fact that Dr. Gottlieb did not appreciate the public health threat to youth until 2018.¹¹⁶ Therefore, he may have skirted the statute, which requires premarket review, to facilitate e-cigarette innovation.¹¹⁷

The U.S. District Court for the District of Maryland seemed to agree with this theory. In a 2019 lawsuit brought by numerous public health organizations and physicians, the Court vacated the guidance postponing e-cigarette premarket review, calling it “tantamount to an amendment to the Tobacco Control Act.”¹¹⁸ The Court explained that FDA’s premarket review authority is not a discretionary one given the use of mandatory language in the TCA.¹¹⁹ In devising a remedy, Judge Grimm acknowledged the severity of the crisis at hand:

The issue is whether this case presents those “extraordinary circumstances” that call for more than a simple remand or vacatur.

. . . .

Given the uncertainty in the efficacy of e-cigarettes as smoking cessation devices, the overstated effects that a shorter deadline may have on manufacturers, the Industry’s recalcitrance, the continued availability of e-cigarettes and their acknowledged appeal to youth, and the clear public health emergency, I find that a deadline is necessary.¹²⁰

He then ordered applications for pre-Deeming Rule products to be submitted

¹¹⁴ U.S. FOOD & DRUG ADMIN., *supra* note 108.

¹¹⁵ See Katie Thomas, *Senate Confirms Scott Gottlieb to Head F.D.A.*, N.Y. TIMES (May 9, 2017), <https://www.nytimes.com/2017/05/09/health/scott-gottlieb-senate-fda-commissioner.html>.

¹¹⁶ Dr. Gottlieb is open about his failure to predict or notice the e-cigarette epidemic until it was too late. See *Statement from FDA Commissioner Scott Gottlieb, M.D., on New Steps to Address Epidemic of Youth E-Cigarette Use*, U.S. FOOD & DRUG ADMIN. (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>. It is unclear whether Dr. Gottlieb was aware of a 2016 CDC report finding that youth e-cigarette use was a “major public health concern” and that youth e-cigarette use grew “an astounding 900%” from 2011 to 2015. 2016 REPORT, *supra* note 12, at vii. In any event, Dr. Gottlieb’s decisions on premarket review were a departure from expertise.

¹¹⁷ Another contributor may be FDA needing more time to prepare premarket review.

¹¹⁸ See *Am. Acad. of Pediatrics*, 379 F. Supp. 3d at 497–98.

¹¹⁹ *Id.* at 494.

¹²⁰ *Am. Acad. of Pediatrics v. FDA*, 399 F. Supp. 3d 479, 483, 486 (D. Md. 2019).

within ten months, by May 2020, and allowed one year for FDA to review applications.¹²¹ (FDA obtained a 120-day extension from the Court due to the novel coronavirus, leaving the final submission deadline as Sept. 9, 2020.)¹²²

Judge Grimm's extraordinary remedy has the potential to bring e-cigarettes within the law and subject them to the premarket review applicable to other tobacco products. However, given that an epidemic is already afoot, the future impact of premarket review is unclear.¹²³

4. *Presidential Control and the Office of Management and Budget*

Of preeminent importance in FDA's efforts to regulate e-cigarettes is the Office of Management and Budget (OMB), an agency within the Executive Office of the President and under White House control. One key division of OMB is the Office of Information and Regulatory Affairs (OIRA), which reviews significant regulatory actions taken by the executive branch. OIRA has become the subject of much critical scholarship.¹²⁴

OIRA is an office of about 45 people and has the power to review "significant" regulatory actions.¹²⁵ An action is "significant" if, *inter alia*, it is probable to result in a rule that could impact the economy by \$100 million or more; adversely affect the economy, jobs, the environment, public health and safety, or any state or local government; or "[r]aise novel legal or policy issues arising out of . . . the President's priorities."¹²⁶ With this language, OIRA may review almost any regulatory action,

¹²¹ *Id.* at 481.

¹²² Stephen M. Hahn, *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*, U.S. FOOD & DRUG ADMIN. (Apr. 23, 2020), <https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-court-grants-fdas-request-extension-premarket-review-submission-deadline>. FDA also appealed the decision to the Fourth Circuit Court of Appeals. Notice of Appeal, *Am. Acad. of Pediatrics v. FDA*, 399 F. Supp. 3d 479 (D. Md. 2019) (No. 8:18-cv-00883-PWG). However, FDA changed course and ratified Judge Grimm's opinion in a 2020 guidance expressing it would enforce on the expedited timeline "[e]ven in the absence of this court order." U.S. FOOD & DRUG ADMIN., *supra* note 57, at 27, 31. E-cigarette manufacturers also successfully moved to intervene for purposes of appeal, but the Fourth Circuit held their claims moot because FDA's 2020 guidance document superseded the 2017 guidance document, and therefore an opinion as to the validity of the 2017 guidance document would be advisory. *In re Cigar Ass'n of Am.*, 812 F. App'x 128, 136 (4th Cir. 2020).

¹²³ Even for tobacco products already subject to premarket review, critics have argued FDA has implemented review in a lenient manner. See Jenson et al., *supra* note 52, at 247–51.

¹²⁴ See, e.g., Lisa Heinzerling, *Statutory Interpretation in the Era of OIRA*, 33 FORDHAM URB. L.J. 1097 (2006); Cass R. Sunstein, *The Office of Information and Regulatory Affairs: Myths and Realities*, 126 HARV. L. REV. 1838 (2013); Eloise Pasachoff, *The President's Budget as a Source of Agency Policy Control*, 125 YALE L.J. 2182 (2016).

¹²⁵ Sunstein, *supra* note 124, at 1845, 1850.

¹²⁶ *Id.* at 1850–51; see also Exec. Order No. 12,866, 3 C.F.R. § 638 (1993).

even on the mere reason the President or her appointees disagree. OIRA's role generally involves reviewing final agency rules, and it has 90 days to decide whether to (1) allow the rule, (2) return the rule to the agency for reconsideration, (3) encourage an agency to withdraw the rule, or (4) seek an extension.¹²⁷ To make its decision, it generally relies on interagency concerns, cost-benefit analysis, and especially presidential priorities.¹²⁸ Because OIRA takes direction from the President,¹²⁹ it may be subject to political influence.

As of late, OIRA and OMB have become increasingly powerful in changing and disapproving federal regulations,¹³⁰ in at least three ways. First, OMB can utilize budgetary authority using numerous "levers" to regulate agencies; for example, after appropriation, agencies do not possess funds until OMB *apportions* then for particular projects or time periods.¹³¹ Second, cost-benefit analysis, an important feature of OIRA review, is susceptible to underlying assumptions, and the Trump Administration has modified these underlying tenets to "ignore or minimize the benefits of regulation," thus emphasizing economic costs and reducing the role of scientific analysis in agency policy decisions.¹³² Under this framework, OIRA is inclined to disapprove more rules. Third, with the increasing lobbying of American government, OMB has taken on a deregulatory role, according to several past administrators.¹³³ Empirical research has found that interest group lobbying of OMB generates

¹²⁷ Sunstein, *supra* note 124, at 1846–47.

¹²⁸ See *id.* at 1847, 1852, 1858, 1869 ("Of course the review process will ask how and if the rule fits with the law and with presidential commitments, goals, and priorities."); Stuart Shapiro, *OIRA's Dual Role and the Future of Cost-Benefit Analysis*, 50 ENVTL. L. REP. 10,385, 10,385 (2020) ("As a result of its location in the Executive Office of the President, and its responsibility for being the 'eyes and ears' of the President when it comes to regulatory policy, it also must ensure that agency regulations are consistent with presidential preferences.").

¹²⁹ See Sunstein, *supra* note 124, at 1874; Stuart Shapiro, *OIRA Inside and Out*, 63 ADMIN. L. REV. 135, 147 (2011) (internal citations omitted) ("[P]residential oversight of the regulatory process is now a permanent institution.").

¹³⁰ See Heinzerling, *supra* note 124, at 1117 ("OIRA's increasingly aggressive role in controlling agency action is so far the biggest administrative law story of the new century. One part of the story is OIRA's role in shaping agencies' interpretations of the laws they administer.").

¹³¹ Pasachoff, *supra* note 124, at 2182, 2228 ("This Article identifies seven levers associated with OMB's work on budget preparation, budget execution, and management and shows how these levers can control agency policymaking. These levers have some salutary aspects, . . . but they also raise a series of accountability concerns related to opacity . . . and the potential for substantive policy (and political) choices to be obscured by technocratic-sounding work.").

¹³² See Shapiro, *supra* note 128, at 10,397.

¹³³ Shapiro, *supra* note 129, at 144–45.

a dose-dependent amount of regulatory change, whereas public interest group lobbying does not have such an effect.¹³⁴ Further, deregulatory and industry groups meet with OIRA far more commonly than pro-regulatory groups.¹³⁵

OMB and OIRA have been a potent blockade to FDA tobacco regulation across Democratic and Republican administrations. According to an L.A. Times investigation, in 2015 Obama's OMB received a finalized Deeming Rule that pulled flavored e-cigarettes, a favorite of youth, from the market.¹³⁶ Over the next two months, OMB engaged in more than 40 meetings with tobacco representatives, and only seven with public health experts.¹³⁷ Industry groups included Vapor Bar (e-cigarette shop), Njoy (tobacco company), Purilum (e-liquid company), Altria (Philip Morris), National Tobacco Company, Molecule Labs, Mid Cities Vapor, VapeNY, Vape A Vet (for veterans), Cuttwood Vapors, and Vapor Shark.¹³⁸ An e-cigarette industry group, the Consumer Advocates for Smoke-Free Alternatives Association (CASAA), brought an 8,790-page packet of e-cigarette testimonials.¹³⁹ This is not to say that these submissions contained valueless information, but that the sheer power and vigor with which the vaping industry opposed the rule outweighed any effort on the other side, and raised in OMB the siren of emergency that the flavor ban would create "an unmitigated disaster" for adults trying to quit smoking.¹⁴⁰

In May 2016, FDA published its final Deeming Rule, but omitted the flavor ban and 15 pages of evidence detailing the role of flavors in driving the youth e-cigarette epidemic.¹⁴¹ Instead, FDA wrote that it wanted "further data on the role of flavored products in youth initiation."¹⁴² The reversal was grounded on the economic harm of banning flavors, the "lifeblood of e-cigarette sales."¹⁴³

After a further surge in youth e-cigarette use and a national epidemic of a new vaping-related lung disease called EVALI,¹⁴⁴ President Trump announced a flavored

¹³⁴ See Simon F. Haeder & Susan Webb Yackee, *Influence and the Administrative Process: Lobbying the U.S. President's Office of Management and Budget*, 109 AM. POL. SCI. REV. 507, 517–18 (2015).

¹³⁵ See Sunstein, *supra* note 124, at 1861.

¹³⁶ See Baumgaertner, *supra* note 77.

¹³⁷ *Id.*

¹³⁸ *Id.*

¹³⁹ *Id.*

¹⁴⁰ See *id.*

¹⁴¹ *Id.*

¹⁴² *Id.*; Deeming Rule, *supra* note 7, at 29,014.

¹⁴³ Baumgaertner, *supra* note 77.

¹⁴⁴ See *Outbreak of Lung Injury Associated with the Use of E-Cigarette, or Vaping, Products*, CTRS. FOR DISEASE CONTROL & PREVENTION (Feb. 25, 2020, 1:00 PM), https://www.cdc.gov/tobacco/basic_information/e-cigarettes/severe-lung-disease.html#what-we-know.

e-cigarette “ban,”¹⁴⁵ administered by FDA through preferential enforcement. However, two months later, he retreated from the ban in response to lobbying and protests, largely driven by economic arguments.¹⁴⁶ While the role of OMB in the most recent flavor ban is unclear, OMB was a major lobbying target of industry during this period.¹⁴⁷

Across the Obama and Trump Administrations, OMB appears to have aided industry representatives in a deregulatory agenda that damaged public health. Twice FDA advanced a flavored e-cigarette ban—an integral measure for protecting youth—only for it to fail at the level of OMB and the White House. OMB has a notable degree of influence over agency regulatory actions, but it is unclear to what extent OMB acted as a political decision-making agent nixing vaping regulations, or simply as a centralized battleground hospitable to industry and presidential prerogatives. Former FDA Commissioner David Kessler has described OMB as a deregulatory instrument of the White House, and has laid out his personal experiences being obstructed by OMB.¹⁴⁸ Cass Sunstein, former OIRA administrator, has argued that OMB/OIRA specializes in “listening,” and meetings with affected industry may have no impact on the final rule.¹⁴⁹ While this may be true in some

¹⁴⁵ Sheila Kaplan, *Trump Administration Plans to Ban Flavored E-Cigarettes*, N.Y. TIMES (Sept. 19, 2019), <https://www.nytimes.com/2019/09/11/health/trump-vaping.html>. As early as 2019, FDA proposed more stringent enforcement against flavored e-cigarettes that appeal to youth. See Angelica LaVito, *FDA Outlines E-Cigarette Rules, Tightens Restrictions on Fruity Flavors to Try to Curb Teen Vaping*, CNBC (Mar. 13, 2019, 3:27 PM), <https://www.cnbc.com/2019/03/13/fda-tightens-restrictions-on-flavored-e-cigarettes-to-curb-teen-vaping.html>; U.S. FOOD & DRUG ADMIN., MODIFICATIONS TO COMPLIANCE POLICY FOR CERTAIN DEEMED TOBACCO PRODUCTS: DRAFT GUIDANCE 4–5, 15 (Mar. 2019), <https://web.archive.org/web/20190313171423/https://www.fda.gov/downloads/TobaccoProducts/Labeling/RulesRegulationsGuidance/UCM633281.pdf>. On the other hand, President Trump’s proposal operated more directly on flavored e-cigarettes, without the burden of proof of showing that a particular brand appealed to youth.

¹⁴⁶ See Joshua M. Sharfstein, *Why the FDA Was Unable to Prevent a Crisis of Vaping Among Kids*, STAT NEWS (Nov. 21, 2019), <https://www.statnews.com/2019/11/21/e-cigarettes-fda-hands-tied>; Josh Dawsey & Laurie McGinley, *Trump Backs off Flavored Vape Ban He Once Touted*, WASH. POST (Nov. 17, 2019, 8:30 PM), https://www.washingtonpost.com/national/health-science/trump-pulls-back-from-flavored-vaping-ban/2019/11/17/30853ece-07ae-11ea-924a-28d87132c7ec_story.html.

¹⁴⁷ See LOBBYING REPORT: LD-2 DISCLOSURE FORM, ALTRIA CLIENT SERVICES LLC (Oct. 21, 2019, 7:06 PM), <https://soprweb.senate.gov/index.cfm?event=getFilingDetails&filingID=07671656-27EC-4F11-B4B7-C8F9CD8BF9C6&filingTypeID=69>; *Client Profile: JUUL Labs*, CTR. FOR RESPONSIVE POLITICS, <https://www.opensecrets.org/federal-lobbying/clients/summary?cycle=2019&id=D000070920> (last visited July 29, 2021).

¹⁴⁸ DAVID KESSLER, A QUESTION OF INTENT: A GREAT AMERICAN BATTLE WITH A DEADLY INDUSTRY 7, 46–48 (2001).

¹⁴⁹ Sunstein, *supra* note 124, at 1861–62.

cases, it appears OMB meetings may have had an impact on vaping rules by amplifying the voice of industry and strengthening political influence over agency expert decision-making. E-cigarettes present a difficult test case for those who argue for agency accountability through White House control.¹⁵⁰ Beyond politicizing an expert decision, it also disempowers youth, who possess no vote with which to hold the President accountable for poor regulation.

The flavored e-cigarette showdown eventually led to a compromise. In January 2020, FDA issued a guidance document exercising enforcement discretion to ban flavored e-cigarettes that use a cartridge refill system (such as Juul), but leaving a “loophole” for disposable and tank-style flavored e-cigarettes.¹⁵¹ Within these exemptions are Puff Bars, which became popular among youth.¹⁵² Puff Bars are disposable flavored e-cigarettes that come in flavors such as strawberry, blue razz, and pineapple lemonade.¹⁵³ The rule also exempted mint and menthol e-cigarettes.¹⁵⁴ Mint and menthol have grown rapidly in popularity among youth, and, as of 2019, 57.3% of high school e-cigarette users sometimes vape menthol or mint.¹⁵⁵ These exemptions detract from the rule’s goal of reducing the attractiveness of e-cigarettes to youth.

C. *Raising the Minimum Purchase Age to 21*

The e-cigarette flavor controversy in late 2019 led to exploration of regulatory alternatives that would not touch adult access. In December 2019, Congress passed a spending bill raising the minimum age of tobacco purchase (including e-cigarettes and combustible cigarettes) from 18 to 21 nationwide.¹⁵⁶ The measure was sup-

¹⁵⁰ Presidential control over agency action is frequently justified as promoting agency accountability to the people. See Nicholas O. Stephanopoulos, *Accountability Claims in Constitutional Law*, 112 NW. U. L. REV. 989, 1010–11 (2018); see also *infra* Section IV.A.

¹⁵¹ See U.S. FOOD & DRUG ADMIN., *supra* note 57, at 3; 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>.

¹⁵² Kaplan, *supra* note 151; Allison Aubrey, *Parents: Teens Are Still Vaping, Despite Flavor Ban. Here's What They're Using*, NPR (Feb. 17, 2020, 5:04 AM), <https://www.npr.org/sections/health-shots/2020/02/17/805972087/teens-are-still-vaping-flavors-thanks-to-new-disposable-vape-pens>.

¹⁵³ See PUFF, <https://puffbar.com> (last visited July 29, 2021).

¹⁵⁴ Kaplan, *supra* note 151.

¹⁵⁵ See Cullen, *supra* note 17, at 2098, 2100–01.

¹⁵⁶ See *Newly Signed Legislation Raises Federal Minimum Age of Sale of Tobacco Products to 21*, U.S. FOOD & DRUG ADMIN. (Jan. 15, 2020), <https://www.fda.gov/tobacco-products/ctp-newsroom/newly-signed-legislation-raises-federal-minimum-age-sale-tobacco-products-21>.

ported by many tobacco companies, which hoped to soothe public anger over e-cigarettes.¹⁵⁷ However, youth purchase of e-cigarettes was already illegal, so the key demographic targeted by this law appears to be people aged 18 to 21. The measure may reduce youth use by impairing informal sales. About half of youth Juul users report obtaining their device from a social source,¹⁵⁸ and youth may not have peers above age 21. The effectiveness of the measure will also depend on enforcement.¹⁵⁹

D. Other Responses to E-Cigarettes

Although the TCA preempts some state and local laws, it explicitly leaves several areas open to state, local, and tribal lawmaking, including regulation of the sale, distribution, and advertising of e-cigarettes.¹⁶⁰ States and municipalities have generally prioritized taxation,¹⁶¹ retail licensure,¹⁶² and smoke-free laws governing spaces such as bars and restaurants.¹⁶³ Given the failure to achieve a national flavored e-cigarette ban, several states, including Michigan, Massachusetts, and New York, issued their own statutory bans.¹⁶⁴ In addition, given the 2019 outbreak of

¹⁵⁷ See Sheila Kaplan, *Congress Approves Raising Age to 21 for E-Cigarette and Tobacco Sales*, N.Y. TIMES (Dec. 19, 2019), <https://www.nytimes.com/2019/12/19/health/cigarette-sales-age-21.html>.

¹⁵⁸ Laura Bach, *Where Do Youth Get Their E-Cigarettes?*, CAMPAIGN FOR TOBACCO-FREE KIDS (Dec. 21, 2019), <https://www.tobaccofreekids.org/assets/factsheets/0403.pdf>.

¹⁵⁹ Kaplan, *supra* note 151.

¹⁶⁰ See Federal Food, Drug, and Cosmetic Act (FDCA) of 1938 § 916, 21 U.S.C. § 387p (2018).

¹⁶¹ See *States with Laws Taxing E-Cigarettes*, PUB. HEALTH LAW CTR. (Sept. 15, 2019), <https://www.publichealthlawcenter.org/sites/default/files/States-with-Laws-Taxing-ECigarettes-September152019.pdf>.

¹⁶² See *States with Laws Requiring Licenses for Retail Sales of E-Cigarettes*, PUB. HEALTH LAW CTR. (Sept. 15, 2019), <https://www.publichealthlawcenter.org/sites/default/files/States-with-Laws-Requiring-Licenses-for-Retail-Sales-of-ECigarettes-September152019.pdf>.

¹⁶³ See *Overview List—Number of Smokefree and Other Tobacco-Related Laws*, AM. NONSMOKERS' RTS. FOUND. (Apr. 1, 2021), <http://no-smoke.org/wp-content/uploads/pdf/mediaordlist.pdf>.

¹⁶⁴ See Laurie McGinley, *Michigan Becomes First State to Ban Flavored E-Cigarettes*, WASH. POST (Sept. 3, 2019, 9:01 PM), <https://wapo.st/3B3bDgx>; Steve Brown & Angus Chen, *What to Know About the New Mass. Law Banning Flavored Vapes and Menthol Cigarettes*, WBUR (Nov. 27, 2019), <https://www.wbur.org/commonhealth/2019/11/27/explainer-flavored-tobacco-vaping-law>; Matthew L. Myers, *New York Takes Historic Action to Tackle Youth E-Cigarette Use by Ending the Sale of All Flavored E-Cigarettes*, CAMPAIGN FOR TOBACCO-FREE KIDS (Apr. 2, 2020), https://www.tobaccofreekids.org/press-releases/2020_04_02_ny-flavored-ecigs.

EVALI,¹⁶⁵ many states issued emergency moratoria on e-cigarette sales.¹⁶⁶ Subsequent court challenges have presented interesting tests of government public health powers.¹⁶⁷ State and local laws are rapidly changing but represent a growing frontier of tobacco regulation.

On the litigation side, Juul faces investigations from FDA, the Federal Trade Commission, federal prosecutors,¹⁶⁸ and a coalition of 39 states.¹⁶⁹ Several states have sued, including New York and California.¹⁷⁰ In October 2019, the Judicial Panel on Multidistrict Litigation initiated multidistrict litigation in the Northern District of California,¹⁷¹ which now comprises about 350 lawsuits, including a nationwide class action representing all Juul customers which “has survived multiple motions to dismiss.”¹⁷² The lawsuits assert numerous claims including consumer fraud, negligence, design defects, public nuisance, and failure to warn.¹⁷³ A full analysis is beyond the scope of this paper.

E. Conclusion

While the TCA offered a historic opportunity to regulate tobacco products, numerous roadblocks from statutory, regulatory, and case-law perspectives provided a window of more than 10 years for e-cigarettes to become a mainstream American product. After the D.C. Circuit rejected FDA jurisdiction over e-cigarettes under the agency’s drug and device authorities, FDA had to resort to jurisdiction under the TCA, which required the establishment of an entirely new regulatory center at

¹⁶⁵ *Outbreak of Lung Injury*, *supra* note 144.

¹⁶⁶ See Jamie Ducharme, *As the Number of Vaping-Related Deaths Climbs, These States Have Implemented E-Cigarette Bans*, TIME (Oct. 11, 2019, 4:28 PM), <https://time.com/5685936/state-vaping-bans>.

¹⁶⁷ See, e.g., Vapor Tech. Ass’n v. Baker, No. SUCV20193102D, 2019 WL 6050041 (Mass. Super. Ct. Oct. 21, 2019) (holding Massachusetts-wide nicotine vape ban expires in one week unless Governor Charlie Baker reissues ban as emergency regulation and holds public hearing), *vacated*, No. SJC-12834, 2019 WL 9048858 (Mass. Dec. 26, 2019).

¹⁶⁸ Julie Creswell & Sheila Kaplan, *How Juul Hooked a Generation on Nicotine*, N.Y. TIMES (Feb. 12, 2020), <https://www.nytimes.com/2019/11/23/health/juul-vaping-crisis.html>.

¹⁶⁹ See Dave Collins & Matthew Perrone, *‘A World of Hurt’: 39 States to Investigate Juul’s Marketing*, AP NEWS (Feb. 25, 2020), <https://apnews.com/article/tn-state-wire-william-tong-lawsuits-tobacco-industry-regulation-mi-state-wire-bc0ebafd2c6604e2ac26c6ee219c35b4>.

¹⁷⁰ Verena Dobnik, *New York Joins States Suing E-Cigarette Maker Juul*, ABC NEWS (Nov. 19, 2019, 10:21 AM), <https://abcnews.go.com/US/wireStory/york-joins-states-suing-cigarette-maker-juul-67134344>.

¹⁷¹ See Transfer Order at 1–2, In re Juul Labs, Inc., Mktg., Sales Practices, & Prods. Liab. Litig., No. 3:19-md-02913-WHO (J.P.M.L. Oct. 2, 2019).

¹⁷² Jeff Overley & Emily Field, *What Attys Should Know As Juul Battles Blaze of Litigation*, LAW360 (Feb. 14, 2020, 7:15 PM), <https://www.law360.com/articles/1213895/what-attys-should-know-as-juul-battles-blaze-of-litigation>.

¹⁷³ *Id.*

FDA and a time-consuming rulemaking process to create the Deeming Rule, a frequent subject of litigation. Ultimately, despite the TCA's clear goal of reviewing tobacco products *before* marketing, e-cigarettes will be reviewed retrospectively, while the epidemic is in full swing, far too late to prevent the disease and suffering as envisioned by the TCA's preamble. Solutions to these legal issues will be provided later.¹⁷⁴

II. IMPORTANT CONTEXTS FOR REGULATING E-CIGARETTES

Much of the discussion surrounding e-cigarettes has come from one of two opposing views. On the one hand, proponents tend to argue that e-cigarettes are safe and offer an off-ramp for people addicted to tobacco products. On the other hand, skeptics and most public health commentators contend that e-cigarettes' safety is false or indeterminate, and e-cigarettes are hurting youth. There has yet to be explored a meaningful historical-legal review to predict the harms of e-cigarettes while managing uncertainty. Importantly, because tobacco products are addicting and addiction may be irreversible as a practical matter, it is essential to build a tobacco regulatory regime based on a strong historical, legal, medical, and public health basis, rather than on ideology. This Part will begin by laying out the harms of e-cigarettes from multiple angles. It will then transition to a discussion of inter-generational equity—the consideration of multiple generations and populations in devising e-cigarette regulation. Finally, it will discuss e-cigarette companies' intent to addict youth and policy implications.

A. Harms

Although the research is still in an early stage, numerous studies and several systematic reviews have been published on the harms of e-cigarettes. This research, coupled with a legal-historical perspective, instructs us to avoid false optimism about e-cigarettes.

1. *The Harms of E-Cigarettes May Not Be Clear for Many Years*

The long-term effects of using e-cigarettes will not be understood for many years, making it impossible to conclude with certainty that e-cigarettes are safer than cigarettes.¹⁷⁵ The rosy view with which some advocates depict e-cigarettes is unwarranted, especially when product optimism may obscure harms of new products. For example, cigarettes were frequently promoted as healthful in the 1930s to

¹⁷⁴ See *infra* Part IV.

¹⁷⁵ Gotts et al., *supra* note 4, at 11 (“We reiterate that, to date, no long term vaping toxicological/safety studies have been done in humans; without these data, saying with certainty that e-cigarettes are safer than combustible cigarettes is impossible.”).

1950s, including by nurses and physicians.¹⁷⁶ Even into the 1940s, the majority of America's doctors smoked.¹⁷⁷ By 1955, lung cancer had grown from a rare condition to the highest cause of death of all cancers; cigarettes were only fully recognized as the cause in the famous Surgeon General's report of 1964.¹⁷⁸ Thus, it took three decades for long-term health effects to manifest and for society to notice them. (Figure 3). The same may be true for e-cigarettes.

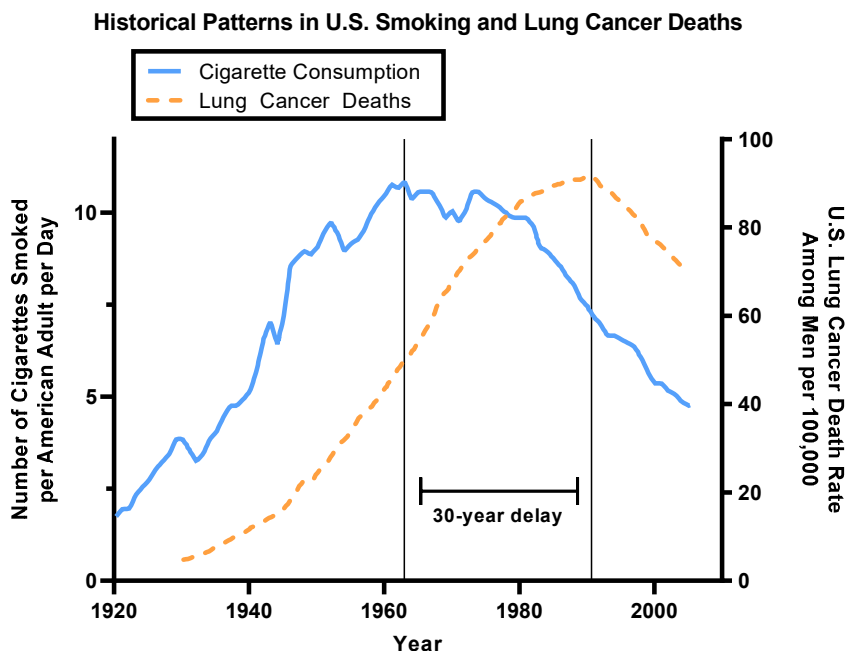


Figure 3: Smoking and lung cancer rates in the U.S.¹⁷⁹

¹⁷⁶ Howard Markel, *Tracing the Cigarette's Path from Sexy to Deadly*, N.Y. TIMES (Mar. 20, 2007), <https://www.nytimes.com/2007/03/20/health/20essay.html> ("Many advertising campaigns from the 1930s through the 1950s extolled the healthy virtues of cigarettes. Full-color magazine ads depicted kindly doctors clad in white coats proudly lighting up or puffing away, with slogans like 'More doctors smoke Camels than any other cigarette.'"); Martha N. Gardner & Allan M. Brandt, "The Doctors' Choice is America's Choice": *The Physician in US Cigarette Advertisements, 1930–1953*, 96 AM. J. PUB. HEALTH 222, 225–29 (2006).

¹⁷⁷ See sources cited *supra* note 176.

¹⁷⁸ See David B. Abrams, Allison M. Glasser, Andrea C. Villanti & Raymond Niaura, *The Rise and Decline But Not Demise of the Greatest Behavioral Health Disaster of the 20th Century*, AGENCY FOR HEALTHCARE RSCH. & QUALITY (2015), <https://www.ahrq.gov/professionals/education/curriculum-tools/population-health/abrams.html>.

¹⁷⁹ This graph was adapted from Prabhat Jha, *Avoidable Global Cancer Deaths and Total Deaths from Smoking*, 9 NATURE REV. CANCER 655, 658 (2009).

Opioids, too, are notable for a rosy view at the start of the epidemic. In the late 1990s, it became widely believed (largely due to marketing) that newer opioids, in particular OxyContin, were less addicting and better at keeping patients consistently pain-free.¹⁸⁰ OxyContin sales boomed between 1996 and 2000, and it became the most abused opioid by 2004, thus laying the foundation of the opioid epidemic.¹⁸¹ The U.S. Department of Health and Human Services declared a public health emergency 13 years later, in 2017.¹⁸² Based on the expected delay of health harms and recognition thereof, e-cigarettes demand caution.

2. *Some Assume E-Cigarettes Are Safer Because There Is No Combustion*

The primary argument for replacing cigarettes with e-cigarettes is that “[m]ost of the harm is due to the inhalation of combustion products.”¹⁸³ Abrams et al., in a landmark 2018 review promoting e-cigarettes, classify tobacco use into four categories with increasing levels of harm: (1) no use, (2) nicotine-replacement therapy (including e-cigarettes), (3) smokeless tobacco, and (4) combusted tobacco.¹⁸⁴ This categorization scheme assumes the conclusion that e-cigarettes are safer simply because there is no combustion. Further, Abrams writes, “E-cigarette aerosol is very different. E-cigarettes do not contain any tobacco and do not produce carbon monoxide.”¹⁸⁵ Why should e-cigarettes be substantially judged on the chemicals they do not contain, when there is mounting evidence of harmful chemicals they do contain?¹⁸⁶ Indeed much of the research cited by Abrams (and other e-cigarette advocates) evaluates a small array of cigarette-related metabolites, usually derived from combustion. Hecht et al., for example, conclude after assessing eight chemicals that

¹⁸⁰ See Kolodny, *supra* note 26, at 562; Harriet Ryan, Lisa Girion & Scott Glover, ‘You Want a Description of Hell?’ OxyContin’s 12-Hour Problem, L.A. TIMES (May 5, 2016), <http://www.latimes.com/projects/oxycontin-part1>.

¹⁸¹ See Art Van Zee, *The Promotion and Marketing of OxyContin: Commercial Triumph, Public Health Tragedy*, 99 AM. J. PUB. HEALTH 221, 221, 225 (2009).

¹⁸² *What Is the U.S. Opioid Epidemic?*, U.S. DEP’T OF HEALTH & HUMAN SERVS., <https://www.hhs.gov/opioids/about-the-epidemic/index.html> (last updated Feb. 19, 2021).

¹⁸³ Abrams et al., *supra* note 1, at 197.

¹⁸⁴ *Id.* at 195.

¹⁸⁵ *Id.* at 197.

¹⁸⁶ See, e.g., Hanan Qasim, Zubair A. Karim, Jose O. Rivera, Fadi T. Khasawneh & Fatima Z. Alshbool, *Impact of Electronic Cigarettes on the Cardiovascular System*, 6 J. AM. HEART ASS’N, Sept. 22, 2017, at 1, 4–5, 10; Donatella Canistro, Fabio Vivarelli, Silvia Cirillo, Clara Babot Marquillas, Annamaria Buschini, Mirca Lazzaretti, Laura Marchi, Vladimiro Cardenia, Maria Teresa Rodriguez-Estrada, Maura Lodovici, Caterina Cipriani, Antonello Lorenzini, Elenora Croco, Andrea Vornoli, Annamaria Colacci, Monica Vaccari, Andrea Sapone & Moreno Paolini, *E-Cigarettes Induce Toxicological Effects that can Raise the Cancer Risk*, 7 SCI. REPS., May 2017, at 1 (“Contrary to the general belief that the lack of tobacco combustion typical of electronic nicotine-delivery systems avoids the production of harmful chemicals, the high temperature reached by e-cig solutions (>200 degrees Celsius) can generate dozens of toxic substances . . .” (footnotes omitted)).

“e-cigarette use may be safer than cigarette smoking. . . .”¹⁸⁷ However, recent research has identified various compounds in e-cigarette liquid that are carcinogenic or known to cause cardiac or pulmonary illness, even if not derived from combustion.¹⁸⁸ The absence of combustion is insufficient to establish the safety of e-cigarettes. In assessing their safety, chemical exposure should be compared not merely with smoking, but also with non-smoking.

3. *Knowledge of E-Cigarettes’ Harms Is Rapidly Evolving*

Vaping advocates tend to view e-cigarettes as competitors of the “much more dangerous cigarettes.”¹⁸⁹ They have pointed to particular limited studies showing e-cigarettes are safer;¹⁹⁰ some journalists have been persuaded.¹⁹¹

However, the rapid rate of discovery of e-cigarettes’ harms should give us pause. According to a 2014 meta-analysis of 29 studies, “[v]arious chemical substances and ultrafine particles known to be toxic, carcinogenic and/or to cause respiratory and heart distress have been identified in e-cigarette aerosols, cartridges, refill liquids and environmental emissions.”¹⁹² According to Chun et al.’s thorough review of the pulmonary impact of e-cigarettes, “there is a rapidly growing body of evidence derived from in vitro, animal, and human studies that e-cigarette use may have significant

¹⁸⁷ See Stephen S. Hecht, Steven G. Carmella, Delshanee Kotandeniya, Makenzie E. Pillsbury, Menglan Chen, Benjamin W. S. Ransom, Rachel Isaksson Vogel, Elizabeth Thompson, Sharon E. Murphy & Dorothy K. Hatsukami, *Evaluation of Toxicant and Carcinogen Metabolites in the Urine of E-Cigarette Users Versus Cigarette Smokers*, 17 NICOTINE & TOBACCO RSCH. 704, 707–08 (2015); see also Maciej L. Goniewicz, Michal Gawron, Danielle M. Smith, Margaret Peng, Peyton Jacob III & Neal L. Benowitz, *Exposure to Nicotine and Selected Toxicants in Cigarette Smokers Who Switched to Electronic Cigarettes: A Longitudinal Within-Subjects Observational Study*, 19 NICOTINE & TOBACCO RSCH. 160, 160, 164 (2017) (evaluating 24 chemicals); Lion Shahab, Maciej L. Goniewicz, Benjamin C. Blount, Jamie Brown, Ann McNeill, K. Udeni Alwis, June Feng, Lanqing Wang & Robert West, *Nicotine, Carcinogen, and Toxin Exposure in Long-Term E-Cigarette and Nicotine Replacement Therapy Users: A Cross-sectional Study*, 166 ANNALS INTERNAL MED. 390, 391, 395 (2017) (evaluating eight chemicals and noting “we focus here on well-established metabolites of compounds that are known to contribute significantly to *smoking-related* toxicologic and carcinogenic risks” (emphasis added)).

¹⁸⁸ NAT’L ACAD. OF SCIS., PUBLIC HEALTH CONSEQUENCES OF E-CIGARETTES 155–56 (Kathleen Stratton, Leslie Y. Kwan & David L. Eaton eds., 2018).

¹⁸⁹ See Peter Hajek, Jonathan Foulds, Jacques Le Houezec, David Sweanor & Derek Yach, *Should E-Cigarettes Be Regulated As a Medicinal Device?*, 1 LANCET: RESPIRATORY MED. 429, 430 (2013).

¹⁹⁰ See, e.g., Shahab et al., *supra* note 187, at 390 (cited by 133 news outlets).

¹⁹¹ See, e.g., Linda Bauld, *The Evidence Keeps Piling Up: E-Cigarettes are Definitely Safer than Smoking*, GUARDIAN (Dec. 29, 2017, 7:00 AM), <https://www.theguardian.com/science/sifting-the-evidence/2017/dec/29/e-cigarettes-vaping-safer-than-smoking>.

¹⁹² See Tianrong Cheng, *Chemical Evaluation of Electronic Cigarettes*, 23 TOBACCO CONTROL, at ii11, ii16 (Supp. 2014).

pulmonary toxicity.”¹⁹³ The more recent Gotts 2019 review concluded there was “likely” pulmonary toxicity given “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”¹⁹⁴ Several reviews have found “concerning” cardiovascular effects, but acknowledge that more data is needed.¹⁹⁵ A 2018 review attributes elevated cardiovascular risk to ultrafine particles, which are the contents of e-cigarette aerosol (it is not just water!), are biologically active, and are implicated in the inflammatory response.¹⁹⁶

While e-cigarettes may be safer than cigarettes, the rapidly developing evidence, tending to show human harms, is a harbinger. The river is flowing with a fairly strong current, perhaps even accelerating. The prospect of this research being a false omen is unlikely, although it is possible e-cigarettes will turn out to be, say, half as harmful as cigarettes.¹⁹⁷ But a product half as harmful as cigarettes is still very deserving of regulation given the extremely large toll tobacco products exact on the health of Americans.

4. *The Stakes Are Extremely High*

Because tobacco products are extremely hazardous to health, the stakes are high. Smoking continues to be the leading cause of preventable death in the United States.¹⁹⁸ Each year, smoking kills half a million Americans,¹⁹⁹ accounting for a little

¹⁹³ See Lauren F. Chun, Farzad Moozed, Carolyn S. Calfee, Michael A. Matthay & Jeffrey E. Gotts, *Pulmonary Toxicity of E-Cigarettes*, 313 AM. J. PHYSIOLOGY-LUNG CELLULAR & MOLECULAR PHYSIOLOGY, at L193, L202 (2017).

¹⁹⁴ Gotts et al., *supra* note 4, at 11.

¹⁹⁵ See Andrea MacDonald & Holly R. Middlekauff, *Electronic Cigarettes and Cardiovascular Health: What Do We Know So Far?*, 15 VASCULAR HEALTH & RISK MGMT. 159, 166, 172 (2019); Holly R. Middlekauff, *Cardiovascular Impact of Electronic-Cigarette Use*, 30 TRENDS IN CARDIOVASCULAR MED. 133, 134 (2020); Qasim et al., *supra* note 186, at 1–9.

¹⁹⁶ See Glantz & Bareham, *supra* note 2, at 224–25.

¹⁹⁷ See, e.g., NAT’L ACAD. OF SCIS., *supra* note 188, at 1; Jacob George, Muhammad Hussain, Thenmalar Vadiveloo, Sheila Ireland, Pippa Hopkinson, Allan D. Struthers, Peter T. Donnan, Faisal Khan & Chim C. Lang, *Cardiovascular Effects of Switching from Tobacco Cigarettes to Electronic Cigarettes*, 74 J. AM. COLL. CARDIOLOGY 3112, 3113 (2019).

¹⁹⁸ Joseph T. Lariscy, *Smoking-Attributable Mortality by Cause of Death in the United States: An Indirect Approach*, 7 SSM—POPULATION HEALTH, Apr. 2019, at 1.

¹⁹⁹ See *Smoking & Tobacco Use: Fast Facts*, *supra* note 23.

less than 20% of all deaths throughout the country.²⁰⁰ More than 16 million Americans live with a chronic disease stemming from smoking.²⁰¹ Therefore, if e-cigarettes are even half as harmful as cigarettes, they could lead to hundreds of thousands of deaths annually and widespread chronic disease.

A public health analysis of e-cigarettes depends enormously on who uses them. Again, assuming arbitrarily that e-cigarettes are half as harmful as cigarettes, adoption by new users who never would have smoked is a catastrophe, whereas adoption by people who smoke, assuming they fully transition, can be a large boon to public health. E-cigarettes' potential for extraordinary harm instructs us to curb through regulation any use beyond what is strictly necessary for people who would like to transition from smoking.

5. *Dual Use Undermines Public Health Gains*

Although e-cigarettes may benefit people who transition from smoking, many Americans have become so-called dual users.²⁰² In a 2018 study examining tobacco use by 40,000 people, it was found that 4.3% of the cohort smoked, 1.4% used e-cigarettes, and 1.3% engaged in dual use.²⁰³ The frequency of dual use suggests that it is a very common trap for e-cigarette users. The study also found that dual use, compared with smoking alone, was associated with increased number of cigarettes smoked (that is, dual users smoked *more*, not less), increased risk of arrhythmia, worse general health, and more difficulty breathing.²⁰⁴ Other research has

²⁰⁰ See SHERRY L. MURPHY, JIAQUAN XU, KENNETH D. KOCHANNEK & ELIZABETH ARIAS, CTRS. FOR DISEASE CONTROL & PREVENTION, MORTALITY IN THE UNITED STATES, 2017, at 6 (Nov. 2018), <https://www.cdc.gov/nchs/data/databriefs/db328-h.pdf>.

²⁰¹ *Smoking & Tobacco Use: Fast Facts*, *supra* note 23.

²⁰² See Middlekauff, *supra* note 195, at 134 ("Most adults (~55%) who use ECs [e-cigarettes] are dual users.").

²⁰³ Julie B. Wang, Jeffrey E. Olgin, Gregory Nah, Eric Vittinghoff, Janine K. Cataldo, Mark J. Pletcher & Gregory M. Marcus, *Cigarette and E-cigarette Dual Use and Risk of Cardiopulmonary Symptoms in the Health eHeart Study*, 13 PLOS ONE, July 2018, at 4; *see also* Albert D. Osei, Mohammadhassan Mirbolouk, Olusola A. Orimoloye, Omar Dzaye, Iftekhar Uddin, Emelia J. Benjamin, Michael E. Hall, Andrew P. DeFilippis, Andrew Stokes, Aruni Bhatnagar, Khurram Nasir & Michael J. Blaha, *Association Between E-Cigarette Use and Cardiovascular Disease Among Never and Current Combustible-Cigarette Smokers*, 132 AM. J. MED. 949, 951–53 (2019) (2016 and 2017 telephone survey data indicated that out of 444,092 participants, 3.5% used e-cigarettes and 2.9% engaged in dual use).

²⁰⁴ Wang et al., *supra* note 203, at 5–7.

found that dual users are exposed to greater levels of toxicants than single users²⁰⁵ and face higher cardiovascular risk.²⁰⁶

Dual use occurs not just among people experimenting with tobacco products, but can arise in therapeutic settings with the explicit goal of transitioning tobacco users away from smoking. For example, the well-known Hajek et al. 2019 randomized controlled trial comparing e-cigarettes with traditional nicotine-replacement therapy (e.g., the patch) found that 18% of smokers assigned to e-cigarettes ceased smoking, compared with 9.9% of smokers assigned to nicotine-replacement therapy.²⁰⁷ This trial was celebrated across the media for proving the benefits of e-cigarettes.²⁰⁸ However, the trial failed to consider dual use, and post-hoc analysis revealed that within the e-cigarette group, dual use was more common than cessation:

For every 100 participants who used the e-cigarette strategy, 18 quit smoking, but 14 of those participants became e-cigarette users. *An additional 25 participants who did not quit smoking became dual users, so the e-cigarette strategy created more dual users than quitters*, and most participants who quit smoking transitioned to vaping. Among participants who were not abstinent, a clinically significant reduction in the number of cigarettes smoked was uncommon.²⁰⁹

The post-hoc analysis brings into doubt that the e-cigarette intervention offered a net benefit to smokers.

Why would a tobacco user continue to consume two products? Personal interviews have provided some answers. Usually, dual users intend to transition, but they sometimes continue smoking because: (1) they still crave it, (2) they feel cigarettes provide a more authentic experience, (3) their goal changes from a full transition to

²⁰⁵ Maciej L. Goniewicz Danielle M. Smith, Kathryn C. Edwards, Benjamin C. Blount, Kathleen L. Caldwell, Jun Feng, Lanqing Wang, Carol Christensen, Bridget Ambrose, Nicolette Borek, Dana van Bommel, Karen Konkel, Gladys Erives, Cassandra A. Stanton, Elizabeth Lambert, Heather L. Kimmel, Dorothy Hatsukami, Stephen S. Hecht, Raymond S. Niaura, Mark Travers, Charles Lawrence & Andrew J. Hyland, *Comparison of Nicotine and Toxicant Exposure in Users of Electronic Cigarettes and Combustible Cigarettes*, 1 JAMA NETWORK OPEN, Dec. 14, 2018, at 1, 10–11.

²⁰⁶ Osei et al., *supra* note 203, at 951–53.

²⁰⁷ Peter Hajek, Anna Phillips-Waller, Dunja Przulj, Francesca Pesola, Katie Myers Smith, Natalie Bisal, Jinshuo Li, Steve Parrott, Peter Sasieni, Lynne Dawkins, Louise Ross, Maciej Goniewicz, Qi Wu & Hayden J. McRobbie, *A Randomized Trial of E-Cigarettes Versus Nicotine-Replacement Therapy*, 380 NEW ENG. J. MED. 629, 629, 632–33 (2019).

²⁰⁸ See, e.g., Jan Hoffman, *E-Cigarettes are Effective at Helping Smokers Quit, a Study Says*, N.Y. TIMES (Jan. 30, 2019), <https://www.nytimes.com/2019/01/30/health/ecigarettes-nicotine-smoking-quit.html>; Alice Park, *E-Cigs More Effective than Nicotine Replacements in Helping Smokers Quit, Study Shows*, TIME (Jan. 30, 2019, 7:36 PM), <https://time.com/5517247/e-cigs-more-effective-helping-smokers-quit-study>.

²⁰⁹ James H. Stein & Claudia E. Korcarz, *E-Cigarettes Versus Nicotine-Replacement Therapy for Smoking Cessation*, 380 NEW ENG. J. MED. 1973, 1973 (2019) (emphasis added).

reduced smoking, (4) they want to consume nicotine where smoking is forbidden, (5) they are rationing their cigarettes, which are more expensive than e-cigarettes, and (6) they want to manage their identity by smoking around people who smoke, while using less-stigmatized e-cigarettes around others.²¹⁰ This research underscores the fact that transitioning to e-cigarettes is no easy task, thanks to numerous barriers that may lead tobacco users into the trap of dual use, possibly putting them at higher health risk than before a transition attempt.

The problem of dual use undermines putative public health gains from vaping. That is, while vaping may help some smokers transition,²¹¹ a roughly equally sized population of smokers may become dual users. Therefore, the advent of e-cigarettes may be hurting the health of many adults, too. Dual use undermines public health gains and disrupts the assumption that smokers will cleanly transition to a new product.

6. *Nicotine Is Particularly Harmful to Children*

E-cigarettes and other tobacco products pose greater harms to kids than adults. Kids are more sensitive to nicotine addiction, and at-risk youth may lose autonomy over use within “1 or 2 days of first inhaling from a cigarette.”²¹² As discussed later in this manuscript, most nicotine dependence begins during youth due to their unique sensitivity (and consequently the marketing aimed at this vulnerable population).²¹³ From a biochemical perspective, the adolescent brain responds to nicotine differently than the adult brain.²¹⁴ Nicotine is so-called because it binds to “nico-

²¹⁰ Lindsay Robertson, Janet Hoek, Mei-Ling Blank, Rosalina Richards, Pamela Ling & Lucy Popova, *Dual Use of Electronic Nicotine Delivery Systems (ENDS) and Smoked Tobacco: A Qualitative Analysis*, 28 TOBACCO CONTROL 13, 14–17 (2019).

²¹¹ See Kaitlyn M. Berry, Lindsay M. Reynolds, Jason M. Collins, Michael B. Siegel, Jessica L. Fetterman, Naomi M. Hamburg, Aruni Bhatnagar, Emelia J. Benjamin & Andrew Stokes, *E-cigarette Initiation and Associated Changes in Smoking Cessation and Reduction: The Population Assessment of Tobacco and Health Study, 2013–2015*, 28 TOBACCO CONTROL 42, 44–45 (2019) (suggesting daily use aids quitting). *But see* Nancy A. Rigotti, Yuchiao Chang, Hilary A. Tindle, Sara M. Kalkhoran, Douglas E. Levy, Susan Regan, Jennifer H.K. Kelley, Esa M. Davis & Daniel E. Singer, *Association of E-Cigarette Use With Smoking Cessation Among Smokers Who Plan to Quit After a Hospitalization*, 168 ANNALS OF INTERNAL MED. 613, 613–14, 619–20 (2018) (finding patients who began using e-cigarettes after hospitalization experienced less tobacco cessation, possibly explained through exclusive e-cigarette use).

²¹² See Natalia A. Goriounova & Huibert D. Mansvelder, *Short- and Long-Term Consequences of Nicotine Exposure During Adolescence for Prefrontal Cortex Neuronal Network Function*, 2 COLD SPRING HARBOR PERSPS. MED., Dec. 2012, at 1, 2.

²¹³ See *infra* Section II.B.

²¹⁴ See Menglu Yuan, Sarah J. Cross, Sandra E. Loughlin & Frances M. Leslie, *Nicotine and the Adolescent Brain*, 593 J. PHYSIOLOGY 3397, 3397 (2015).

tinic acetylcholine receptors” in the brain, thereby catalyzing various neuronal cascades.²¹⁵ In adolescents, nicotine produces more stimulation of these receptors in reward-related areas of the brain.²¹⁶ Nicotine, more in youth than adults, can induce strong consistent signals (long-term potentiation) in dopamine neurons in the ventral tegmental area.²¹⁷ This dopamine neuron sensitivity suggests that youth may experience greater positive feelings through tobacco use.²¹⁸ Adolescent rats exposed to IV nicotine readily learn to press a lever delivering more nicotine, and they take more nicotine than adults.²¹⁹ The earlier an adolescent begins to use tobacco products, the less likely they will be able to quit, and the more tobacco they will use in the future, on average.²²⁰ According to Professors Natalia Goriounova and Huibert Mansvelder:

[M]ost likely owing to its ongoing development, the adolescent brain is more vulnerable to the effects of nicotine than the adult brain. Adolescents progress faster to nicotine dependence than adults, find nicotine more rewarding, underestimate the risks of smoking, and are more influenced by smoking behavior in their social milieu.²²¹

However, nicotine is not just potent to young brains; it is actively harmful to them. For one, according to the “gateway” theory, e-cigarettes serve as an on-ramp to other substances, including cigarettes. E-cigarette use is positively associated with alcohol, marijuana, and illicit drug use.²²² Although an association is susceptible to critiques about causation, more sophisticated temporal research designs have shown that youth who use e-cigarettes are more likely to later initiate tobacco use.²²³ There

²¹⁵ See Lorena M. Siqueira, *Nicotine and Tobacco as Substances of Abuse in Children and Adolescents*, 139 PEDIATRICS, Jan. 1, 2017, at e1, e4.

²¹⁶ Yuan et al., *supra* note 214, at 3403.

²¹⁷ *Id.*

²¹⁸ See Patrick Zickler, *Nicotine’s Multiple Effects on the Brain’s Reward System Drive Addiction*, NAT’L INST. ON DRUG ABUSE (Mar. 1, 2003), <https://archives.drugabuse.gov/news-events/nida-notes/2003/03/nicotines-multiple-effects-brains-reward-system-drive-addiction> (“[N]icotine, like other addictive drugs, attaches to the core neurons of the brain’s reward system, where beneficial behaviors (such as drinking water when thirsty) are rewarded and reinforced.”).

²¹⁹ Yuan et al., *supra* note 214, at 3403–04.

²²⁰ Siqueira, *supra* note 215, at e2.

²²¹ Goriounova & Mansvelder, *supra* note 212, at 3.

²²² See, e.g., Vrati M. Mehra, Asvini Keethakumar, Yvonne M. Bohr, Peri Abdullah & Hala Tamim, *The Association Between Alcohol, Marijuana, Illegal Drug Use and Current Use of E-cigarette Among Youth and Young Adults in Canada: Results from Canadian Tobacco, Alcohol and Drugs Survey 2017*, 19 BMC PUB. HEALTH, Sept. 2, 2019, at 2, 5; Nicholas Chadi, Rachel Schroeder, Jens Winther Jensen & Sharon Levy, *Association Between Electronic Cigarette Use and Marijuana Use Among Adolescents and Young Adults: A Systematic Review and Meta-Analysis*, 173 JAMA PEDIATRICS, Oct. 2019, at 6.

²²³ See Kaitlyn M. Berry, Jessica L. Fetterman, Elemia J. Benjamin, Aruni Bhatnagar, Jessica L. Barrington-Trimis, Adam M. Leventhal & Andrew Stokes, *Association of Electronic Cigarette*

is still the possibility that a common risk factor, such as poor mental health, could explain both e-cigarette and other substance use.²²⁴ However, one recent study identified a biological mechanism, via the FosB gene, by which nicotine appears to facilitate dependence to other drugs.²²⁵ While more research is needed, e-cigarettes do generate nicotine dependence which likely increases the odds of later cigarette use, and e-cigarettes possibly potentiate addiction to other substances.²²⁶

Nicotine on its own, even absent other substances, is harmful to the adolescent brain. Nicotine impairs working memory and attention in adolescents, and it can reduce activation of the prefrontal cortex, the part of the brain responsible for higher-order thinking.²²⁷ Nicotine, more in adolescents than adults, upregulates the quantity of nicotinic acetylcholine receptors, changes the structure of neurons in the prefrontal cortex, and causes phosphorylation and activation of multiple cell signaling pathways.²²⁸ Adolescent tobacco use is associated with developing mental disorders such as depression and panic attacks, as well as behavioral problems and academic problems.²²⁹ While researchers have yet to clarify the full mechanism by which nicotine influences the brain and causes downstream harm, numerous studies have found acute and chronic effects of nicotine on the brain, which FDA has utilized as justification for regulation.²³⁰

The special sensitivity to nicotine of the adolescent brain justifies being particularly cautious about youth accessing e-cigarettes. Adults who wish to expand access to e-cigarettes risk addicting those with fundamentally different and vulnerable brain chemistry.

Use with Subsequent Initiation of Tobacco Cigarettes in US Youths, 2 JAMA NETWORK OPEN, Feb. 1, 2019, at 1, 5; Michael S. Dunbar, Jordan P. Davis, Anthony Rodriguez, Joan S. Tucker, Rachana Seelam & Elizabeth J. D'Amico, *Disentangling Within- and Between-Person Effects of Shared Risk Factors on E-Cigarette and Cigarette Use Trajectories from Late Adolescence to Young Adulthood*, 21 NICOTINE & TOBACCO RSCH. 1414, 1414, 1421 (2019).

²²⁴ See Kira E. Riehm, Andrea S. Young, Kenneth A. Feder, Noa Krawczyk, Kayla N. Tormohlen, Lauren R. Pacek, Ramin Mojtabai & Rosa M. Crum, *Mental Health Problems and Initiation of E-Cigarette and Combustible Cigarette Use*, PEDIATRICS, July 1, 2019, at 1, 6.

²²⁵ Siqueira, *supra* note 215, at e4–e5.

²²⁶ See Yuan et al., *supra* note 214, at 3397 (“We argue that nicotine exposure, increasingly occurring as a result of e-cigarette use, may induce epigenetic changes that sensitize the brain to other drugs and prime it for future substance abuse.”).

²²⁷ See Goriounova & Mansvelder, *supra* note 212, at 6.

²²⁸ *Id.* at 4–5.

²²⁹ *Id.* at 6–7.

²³⁰ See *Think E-Cigs Can't Harm Teens' Health?*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/tobacco-products/public-health-education/think-e-cigs-cant-harm-teens-health> (last updated Apr. 30, 2020).

7. *Financial Harms, Distributional Consequences, and Vulnerable Groups*

Beyond health harms, tobacco products harm users financially and raise serious distributional implications. By any measure, tobacco use is expensive. The vast majority of smokers are daily smokers, who spend an average of \$1,845 annually on cigarettes (at an average of \$7.22 per pack).²³¹ This is just a few hundred dollars less than what the average household spends annually on gas.²³² When considering that smoking is 80% more common at or below the poverty line than above it,²³³ the economic harm from smoking is even more striking. Smoking is associated with considerable financial stress; financial stress increases with the quantity smoked and is especially prominent in low-income smokers.²³⁴ Those who experience financial strain have worse cessation rates and more relapse,²³⁵ suggesting that smoking and financial strain create a self-reinforcing cycle.

Not only the financially insecure, but many other vulnerable populations smoke at greater rates. Consider the following comparisons between more and less vulnerable groups:

²³¹ The average price per pack in the United States is \$7.22, although it varies by state from \$5.51 in Missouri to \$11.29 in Washington, D.C. See ANN BOONN, CAMPAIGN FOR TOBACCO-FREE KIDS, STATE EXCISE AND SALES TAXES PER PACK OF CIGARETTES: TOTAL AMOUNTS & STATE RANKINGS (Mar. 15, 2021), <https://www.tobaccofreekids.org/assets/factsheets/0202.pdf>. As of 2016, 76.1% of smokers were daily smokers, and these smokers tended to smoke 14.1 cigarettes per day (about 70% of a pack). Ahmed Jamal, Elyse Phillips, Andrea S. Gentzke, David M. Homa, Stephen D. Babb, Brian A. King & Linda J. Neff, *Current Cigarette Smoking Among Adults—United States, 2016*, 67 MORBIDITY & MORTALITY WKLY REP. 53, 55 (2018). Thus, the calculation for annual cost was $\$7.22 \times 70\% \times 365 \approx \$1,845$. There are ways for cigarette purchasers to evade taxes or purchase in bulk, which were not considered in the calculations.

²³² See U.S. BUREAU OF LAB. STATS., CONSUMER EXPENDITURES REPORT 2019, at 2 (Dec. 2020), <https://www.bls.gov/opub/reports/consumer-expenditures/2019/pdf/home.pdf> (in 2019, the average U.S. consumer spent \$2,094 on “[g]asoline, other fuels, and motor oil”).

²³³ Rachel Widome, Anne M. Joseph, Patrick Hammett, Michelle Van Ryn, David B. Nelson, John A. Nyman & Steven S. Fu, *Associations Between Smoking Behaviors and Financial Stress Among Low-Income Smokers*, 2 PREVENTIVE MED. REPS. 911, 911 (2015).

²³⁴ *Id.* at 913–14; M. Siahpush, R. Borland & M. Scollo, *Smoking and Financial Stress*, 12 TOBACCO CONTROL, Mar. 2003, at 3–4.

²³⁵ Darla E. Kendzor, Michael S. Businelle, Tracy J. Costello, Yessenia Castro, Lorraine R. Reitzel, Ludmila M. Cofta-Woerpel, Yisheng Li, Carlos A. Mazas, Jennifer Irvin Vidrine, Paul M. Cinciripini, Anthony J. Greisinger & David W. Wetter, *Financial Strain and Smoking Cessation Among Racially/Ethnically Diverse Smokers*, 100 AM. J. PUB. HEALTH 702, 702, 705 (2010); Rosemary Hiscock, Ken Judge & Linda Bauld, *Social Inequalities in Quitting Smoking: What Factors Mediate the Relationship Between Socioeconomic Position and Smoking Cessation?*, 33 J. PUB. HEALTH 39, 42 (2011).

Population	% who currently smoke	Comparator	% who currently smoke
Native Americans	31.8%	White Americans	16.6%
Medicaid enrollees	25.3%	Privately insured	11.8%
Uninsured adults	28.4%	Privately insured	11.8%
Disabled	21.2%	Non-disabled	14.4%
Lesbian, gay, bisexual adults	20.5%	Other adults	15.3%
Severe psychological distress	35.8%	No severe psychological distress	14.7%

Table 2: Smoking rates in vulnerable populations vs. comparator populations.²³⁶

Therefore, payments for tobacco products largely operate as a bulk payment from vulnerable groups to corporations, their directors and officers, their lawyers, and their shareholders, all of whom represent higher-income people. The size of the annual payment (in 2016, by daily smokers, for simplicity) is roughly the number of people who smoke daily multiplied by the average annual per-capita cost of buying cigarettes.²³⁷

324,230,564 [U.S. population] × 11.8% [percentage of Americans who are daily smokers] × \$1,845

= \$70,588,236,088.44

≈ \$71 billion

This estimate is conservative and only considers daily smokers; in fact, American tobacco companies earned revenues of \$117 billion in 2016.²³⁸ The financial cost of addiction has immense distributional consequences through a monetary

²³⁶ Jamal et al., *supra* note 231, at 55–56.

²³⁷ The data are from *id.* at 55 and *U.S. and World Population Clock*, U.S. CENSUS BUREAU, <https://www.census.gov/popclock> (last visited July 29, 2021), entered date as June 15, 2016. The sum does not include non-daily smokers. About 5% of the total sum likely goes to taxes. See BOONN, *supra* note 231.

²³⁸ Jennifer Maloney & Saabira Chaudhuri, *Against All Odds, the U.S. Tobacco Industry Is Rolling in Money*, WALL STREET J. (Apr. 23, 2017), <https://www.wsj.com/articles/u-s-tobacco-industry-rebounds-from-its-near-death-experience-1492968698?mod=rsswn>. These revenues include international sales and sales of non-cigarette tobacco products.

transfer of more than \$65 billion each year from disproportionately vulnerable Americans.

The e-cigarette industry has not attained the financial wherewithal of the cigarette industry, but it is rapidly growing. U.S. sales of e-cigarettes climbed from \$2.5 billion in 2014²³⁹ to \$7 billion in 2019.²⁴⁰ While an average pack of cigarettes costs \$7.19,²⁴¹ the equivalent in e-cigarettes costs around \$4 (and the device costs about \$15).²⁴² While e-cigarettes may appear to be money-saving, two problems cut against this conclusion. First, youth who become addicted to e-cigarettes will suffer financial consequences for the rest of their lives. Second, for adults, it is unclear whether those transitioning will have to use more e-cigarette fluid to satisfy cravings, or whether the tendency for people who try e-cigarettes to become dual users may lead to higher costs overall.²⁴³ In any event, e-cigarettes represent a burgeoning industry, and this money is largely drawn from addicted people.

The distributive impact of e-cigarettes will likely worsen over time as e-cigarettes become increasingly marketed to vulnerable groups,²⁴⁴ and as privileged people addicted to e-cigarettes have superior access to treatment.²⁴⁵ Minimal research has been published on e-cigarette use by vulnerable populations other than youth. At this point, it appears e-cigarette use is not stratified by income or race.²⁴⁶

²³⁹ 2016 REPORT, *supra* note 12, at 149.

²⁴⁰ Katie Thomas & Sheila Kaplan, *E-Cigarettes Went Unchecked in 10 Years of Federal Inaction*, N.Y. TIMES (Nov. 1, 2019), <https://www.nytimes.com/2019/10/14/health/vaping-e-cigarettes-fda.html>.

²⁴¹ BOONN, *supra* note 231.

²⁴² A pack of four Juul “pods,” each equivalent to a pack of cigarettes, costs around \$15.99 at 5% nicotine concentration. James Wellemeier, *Teens Can Spend \$1,000 a Year on Vaping—And the Crackdown on Juul is Making it More Expensive*, MARKETWATCH (June 29, 2019, 7:58 AM), <https://www.marketwatch.com/story/a-crackdown-on-juul-made-vaping-more-expensive-for-some-teens-2019-06-24>; *Menthol*, JUUL.COM (2019), <https://www.juul.com/shop/pods/menthol-5-percent> [<https://perma.cc/WDU4-AJFJ>] (entered state of residence as Ohio). As evidenced by a comparison of the number of reviews, it appears the 3% strength version is rarely purchased (as of May 2021, there were 776 reviews for 3% compared with 2843 reviews for 5%). See *Menthol*, *supra* note 242. The device costs \$14.99, although it is unclear how often the device must be replaced. See *Slate Juul Device*, JUUL.COM (2019), <https://www.juul.com/shop/devices/basic-kit> [<https://perma.cc/75B8-M7Q8>].

²⁴³ See *supra* Section II.A.5.

²⁴⁴ See Amanda Fallin-Bennett, Mollie Aleshire, Traci Scott & Youn Ok Lee, *Marketing of E-Cigarettes to Vulnerable Populations: An Emerging Social Justice Issue*, 55 PERSPS. PSYCHIATRIC CARE 584, 584 (2019).

²⁴⁵ See Jonathan W. Koma, Julie M. Donohue, Colleen L. Barry, Haiden A. Huskamp & Marian Jarlenski, *Medicaid Coverage Expansions and Cigarette Smoking Cessation Among Low-Income Adults*, 55 MED. CARE 1023, 1023 (2017) (“Without Medicaid coverage, most low-income adults have little access to care, including smoking cessation services.”).

²⁴⁶ See Alyssa F. Harlow, Andrew Stokes & Daniel R. Brooks, *Socioeconomic and Racial/Ethnic Differences in E-Cigarette Uptake Among Cigarette Smokers: Longitudinal Analysis of*

However, e-cigarette companies have begun targeting vulnerable groups through disseminating advertisements on such themes as LGBTQ+ pride, Martin Luther King, and feminism.²⁴⁷ For example, one e-cigarette company sponsoring the Miami Beach LGBTQ Pride festival explained:

This weekend, April 11 to 13, is all about pride . . . [E]xpect to see VaporZone making a grand presence, as they will be one of the event sponsors. Spreading the word and the vaping love, we hope to have everyone enjoying these awesome e-cigarettes in the spirit of pride and unity.²⁴⁸

As these marketing practices continue, and privileged people disproportionately escape addiction, the direct distributive impact of e-cigarettes on vulnerable populations will likely grow.

However, the distributive impact of tobacco extends beyond direct monetary transfers to tobacco companies. In the case of cigarettes, vulnerable groups pay for cigarettes directly with their health. People who smoke may suffer from numerous medical diseases and often early death.²⁴⁹ These illnesses exact a heavy physical and emotional toll on those who are already disadvantaged. Resulting disabilities may impact the ability to work.²⁵⁰ On the other hand, the financial beneficiaries of tobacco purchases are likely shareholders and people directly participating in the tobacco enterprise. These privileged individuals benefit financially from tobacco sales,²⁵¹ and are less likely, due to their income and privilege, to use tobacco products, as discussed above. So, the health costs of tobacco products create a self-compounding distributive impact through poor health, early death, and worsened working ability, and a distributive benefit to more privileged individuals. While some of these disparities and compounding harms have not emerged for e-cigarettes, there is little reason why e-cigarettes would avoid falling into the same pattern.

The healthcare costs of tobacco also fall largely on low- and middle-income people. This may seem counterintuitive in that all Americans pay taxes. However, Professor Christopher T. Robertson outlines a complex argument showing that

the Population Assessment of Tobacco and Health (PATH) Study, 21 NICOTINE & TOBACCO RSCH. 1385, 1389 (2019).

²⁴⁷ Fallin-Bennett et al., *supra* note 244, at 587–90.

²⁴⁸ *Id.* at 590 (quoting *VaporZone News!*, INT'L VAPOR GROUP (2016), <http://blog.internationalvapor.com/vaporzone-news> [<https://perma.cc/Q4XW-2XJL>]).

²⁴⁹ Robert West, *Tobacco Smoking: Health Impact, Prevalence, Correlates and Interventions*, 32 PSYCHOL. & HEALTH 1018, 1019–21 (2017).

²⁵⁰ Michael T. Halpern, Richard Shikiar, Anne M. Rentz & Zeba M. Khan, *Impact of Smoking Status on Workplace Absenteeism and Productivity*, 10 TOBACCO CONTROL 233, 233 (2001).

²⁵¹ About half of Americans hold no money in the stock market, suggesting substantial investment in the stock market is a privilege. See Patricia Cohen, *We All Have a Stake in the Stock Market, Right? Guess Again*, N.Y. TIMES (Feb. 8, 2018), <https://www.nytimes.com/2018/02/08/business/economy/stocks-economy.html>.

healthcare finance is regressive in several ways.²⁵² First, because employer-based health care is paid for as a flat amount from the paycheck, Americans are essentially buying health insurance out-of-pocket.²⁵³ Thus, people who earn less must pay a greater percentage of their income for health care. Second, the modern rise of deductibles and copays, which require the insured to pay fixed amounts toward their health care, disproportionately burden lower-income people compared to those who earn a higher income.²⁵⁴ Third, these deductibles and copays particularly lead lower-income people to consume less care; thus not only do lower-income workers pay a larger percentage of their income, but they enjoy less the benefits of health care.²⁵⁵ However, missing care can be especially deadly for a smoker, who may develop lung cancer or heart disease (or many other health problems), which require treatment. A smoker who seeks care in the face of high-cost exposure through deductibles and coinsurance may face greater financial harms simply for being sicker. Finally, tobacco use may legally and permissibly factor into health insurance premiums on the Affordable Care Act²⁵⁶ exchanges despite the fact that most other forms of price discrimination, including on the basis of other addictions or diseases, are illegal.²⁵⁷ As e-cigarettes are tobacco products, insurers can charge e-cigarette users larger premiums. Fundamentally, because of how we have structured healthcare finance, the distributive impact of tobacco is far more harmful to vulnerable groups than it ought to be.

Underprivileged groups pay for tobacco with money. They pay for tobacco with their health. And they suffer the lion's share of the healthcare costs, while enjoying fewer of the benefits. The distributive harm of tobacco to vulnerable groups is large.

8. Conclusion

E-cigarettes present the specter of numerous harms, some known, some yet to be fully elucidated. A review of the history of tobacco products and the relevant medical and public health literature reveals that e-cigarettes are far from a harmless product, and instead will likely be shown to be more and more harmful with time, from both health and equity standpoints. To the extent that e-cigarettes nonetheless offer benefits to some smokers, the resulting regulatory dilemma will be explored next.

²⁵² See CHRISTOPHER T. ROBERTSON, EXPOSED: WHY OUR HEALTH INSURANCE IS INCOMPLETE AND WHAT CAN BE DONE ABOUT IT 131 (2019).

²⁵³ *Id.*

²⁵⁴ *Id.*

²⁵⁵ *Id.* at 131–32.

²⁵⁶ Patient Protection and Affordable Care Act, Pub. L. No. 111-148, 124 Stat. 119, 155 (Mar. 23, 2010) (codified as amended in scattered sections of 26 and 42 U.S.C.).

²⁵⁷ See 42 U.S.C. § 300gg(a)(1)(A) (2018). Tobacco users may pay up to 150% of what non-users pay for health insurance premiums. *Id.* § 300gg(a)(1)(A)(iv).

B. Intergenerational Equity

Part of the difficulty in regulating e-cigarettes is that, unlike cigarettes, they offer benefits and harms that differ across subpopulations.

1. Youth and Adults

On the one hand, youth e-cigarette use is mushrooming, and in 2019, 27.5% of all high schoolers used e-cigarettes, compared with 11.7% in 2017.²⁵⁸ The tobacco advocacy group Truth Initiative has set up a text-based e-cigarette cessation program for youth, which drew more than 31,000 signups in its first two months.²⁵⁹ Teenagers have shared near-death stories from vaping²⁶⁰ as well as their struggles with e-cigarette addiction.²⁶¹ The New York Times told the story of 17-year-old Matt Murphy who experienced “love at first puff”:

A skeptical Matt Murphy saw his first Juul at a high school party in the summer of 2016 Everyone knew better than to smoke cigarettes. But a few were amusing themselves by blowing voluptuous clouds with clunky vapes that had been around since middle school. This Juul looked puny in comparison. Just try it, his friend urged. It’s awesome. Matt, 17, drew a pleasing, minty moistness into his mouth. Then he held it, kicked it to the back of his throat and let it balloon his lungs. Blinking in astonishment at the euphoric power-punch of the nicotine, he felt it—what he would later refer to as “the head rush.”

. . . .

So began a toxic relationship with an e-cigarette that would, over the next two years, develop into a painful nicotine addiction that drained his savings, left him feeling winded when he played hockey and tennis, put him at snappish

²⁵⁸ See Angelica LaVito, *CDC Says Teen Vaping Surges to More than 1 in 4 High School Students*, CNBC (Sept. 12, 2019, 10:53 AM), <https://www.cnn.com/2019/09/12/cdc-says-teen-vaping-surges-to-more-than-1-in-4-high-school-students.html>; see also Susan C. Walley, Karen M. Wilson, Jonathan P. Winickoff & Judith Groner, *A Public Health Crisis: Electronic Cigarettes, Vape, and JUUL*, PEDIATRICS, June 2019, at 1 (“Electronic cigarettes (e-cigarettes) and vape devices have rapidly become the most common tobacco products used by youth, driven in large part by marketing and advertising by e-cigarette companies.”).

²⁵⁹ See Jamie Ducharme, *As Kids Get Hooked on Vaping, Parents Are Desperate for Treatment That Doesn’t Exist*, TIME (Mar. 21, 2019, 10:00 AM), <https://time.com/5549340/vaping-addiction-treatment>.

²⁶⁰ See Diane J. Cho, *9 People Who Nearly Died from Vaping-Related Illnesses Share Their Harrowing Stories*, PEOPLE (Nov. 26, 2019, 10:53 AM), <https://people.com/health/vaping-related-illness-stories/?slide=7307211#7307211>.

²⁶¹ See, e.g., Luka Kinard & A. Pawlowski, *16-Year-Old Went to Rehab for Vaping Addiction: ‘I Was out of Control’*, TODAY (Sept. 16, 2019, 9:56 AM), <https://www.today.com/health/16-year-old-went-rehab-vaping-addiction-i-was-out-t162646> (“Luka Kinard, 16, started vaping in high school. His habit grew so out of control that he began selling his clothes to be able to keep buying e-cigarette pods.”).

odds with friends who always wanted to mooch off his Juul and culminated in a shouting, tearful confrontation with his parents.²⁶²

On the other hand, vaping may offer tangible benefits for people who wish to transition from smoking, as evidenced by several studies,²⁶³ with the caveats that vaping may spur dual use²⁶⁴ or encourage relapse among former smokers.²⁶⁵ The potential benefits of transitioning to a safer—but still harmful—product is called “harm reduction.” Testimonials detail the experiences of people who transitioned to vaping.²⁶⁶ Stephanie Rafanelli wrote about how e-cigarettes changed her life:

Well, not exactly cured; it was more of a switching of allegiance. The e-cig worked because it replicated the smoking action that was so deeply entrenched in my psyche. . . . The sensation was the same: the all-important inhale/exhale accompanied by a nicotine hit without the killer chemicals, tar and carbon monoxide. My nighttime wheeze subsided, my hair smelt permanently salon-fresh, and I was, apparently, much nicer to kiss in the mornings.²⁶⁷

One e-cigarette user said his lungs began sounding clear to stethoscope one year after transitioning to vaping.²⁶⁸ The American Vaping Association, though biased toward promoting e-cigarettes, does have a “Testimonials” section of people who

²⁶² Jan Hoffman, *The Price of Cool: A Teenager, a Juul and Nicotine Addiction*, N.Y. TIMES (Nov. 16, 2018), <https://www.nytimes.com/2018/11/16/health/vaping-juul-teens-addiction-nicotine.html>.

²⁶³ See Ramchandrar Gomajee, Fabienne El-Khoury, Marcel Goldberg, Marie Zins, Cedric Lemogne, Emmanuel Wiernik, Emeline Lequy-Flahault, Lucile Romanello, Isabelle Kousignian & Maria Melchior, *Association Between Electronic Cigarette Use and Smoking Reduction in France*, 179 JAMA INTERNAL MED. 1193, 1194 (2019); Berry et al., *supra* note 211, at 44–45; Jamie Hartmann-Boyce, Hayden McRobbie, Chris Bullen, Rachna Begh, Lindsay F. Stead & Peter Hajek, *Electronic Cigarettes for Smoking Cessation*, COCHRANE DATABASE OF SYSTEMATIC REV. 1–2 (2016); Hajek et al., *supra* note 207, at 634. *But see* Stein & Korcarz, *supra* note 209; Belinda Borrelli & George T. O'Connor, *E-Cigarettes to Assist with Smoking Cessation*, 380 NEW ENG. J. MED. 678, 678–79 (2019).

²⁶⁴ See *supra* Section II.A.5.

²⁶⁵ See Gomajee et al., *supra* note 263, at 1194.

²⁶⁶ See, e.g., Paula Span, *Some Older Smokers Turn to Vaping. That May Not Be a Bad Idea.*, N.Y. TIMES (Dec. 8, 2017), <https://www.nytimes.com/2017/12/08/health/smokers-vaping-ecigarettes-elderly.html> (describing woman in her 70s who transitioned to vaping).

²⁶⁷ Stephanie Rafanelli, *How E-Cigarettes Changed My Life*, GUARDIAN (Jan. 3, 2014, 1:50 PM), <https://www.theguardian.com/society/2014/jan/03/how-e-cigarettes-changed-my-life>.

²⁶⁸ See Tanner Stening, ‘We’re not Big Tobacco Like Juul’; Gov. Charlie Baker’s Vape Ban Draws Ire at Public Hearing, MASSLIVE (Nov. 22, 2019), <https://www.masslive.com/news/2019/11/were-not-big-tobacco-like-juul-gov-charlie-bakers-vape-ban-draws-ire-at-public-hearing.html>.

transitioned.²⁶⁹ Therefore, if the debate is to be conceived as two opposing sides, which is undoubtedly a simplification, then both sides are marshaling evidence, both scientific and anecdotal.

Ultimately, because it is likely that e-cigarettes carry both harms and benefits to different populations, there arise issues of intergenerational equity. Intergenerational equity “distributes well-being through time, ensuring the well-being of present and future generations of a population or nation.”²⁷⁰ The principle requires that regulatory decision-making consider the welfare of both youth and adults. Therefore, some e-cigarette advocates’ broad denunciations of regulation improperly ignore youth. For example, British advocate and psychologist Dr. Peter Hajek has argued:

[S]ince ECs [e-cigarettes] are a recreational consumer product that are competing with much more dangerous cigarettes, which are not regulated as medicines, mandatory medicinal regulation is not required for public safety and can harm public health by restricting the ability of ECs to compete with cigarettes in the marketplace. . . . Regulators of medicines [e.g., FDA] should hold their fire.²⁷¹

This analysis assumes that e-cigarettes operate as a “harm reduction” device and forgets that they can (and have) become a major cause of initiation of tobacco products, particularly among youth. The concept of intergenerational equity questions whether a product can be considered as supporting harm reduction if it harms one group to benefit another.²⁷² Unfortunately, the conflicting impact of e-cigarettes on different groups has enabled the coalescing of interest groups and strewn division in discussions on vaping, in which people can accuse one another of taking lives or

²⁶⁹ See *Testimonials*, AM. VAPING ASS’N, <https://vaping.org/read-testimonials> (last visited July 29, 2021).

²⁷⁰ J. K. Summers & L. M. Smith, *The Role of Social and Intergenerational Equity in Making Changes in Human Well-Being Sustainable*, 43 *AMBIO* 718, 718 (2014).

²⁷¹ See Hajek et al., *supra* note 189, at 430–31.

²⁷² See Aruni Bhatnagar, Thomas J. Payne & Rose Marie Robertson, *Is There a Role for Electronic Cigarettes in Tobacco Cessation?*, J. AM. HEART ASS’N, June 18, 2019, at 1 (“The easy accessibility of e-cigarettes and the perception that they are reduced-harm products has led to the recruitment of a new group of nicotine-addicted youth, otherwise at low risk for tobacco use, who are ultimately more likely to transition from e-cigarettes to combustible cigarettes.”).

damaging public health.²⁷³ Particularly problematic is the increase in lobbying expenditures and financial might dedicated to shielding e-cigarettes from health-promoting regulation.²⁷⁴

Effective implementation of e-cigarettes as a harm reduction tool requires regulation ensuring their use only by smokers,²⁷⁵ ideally recommended as a second-line means of smoking cessation.²⁷⁶ Particularly relevant here is the work of bioethicist Travis N. Rieder, who posits in the opioid context that pain medications carry both benefits and harms to different populations.²⁷⁷ He then argues that opioids should be accessible to pain patients yet regulated to minimize harms to others:

[T]here will be costs to any solution. . . . But taking seriously *everyone's* story, and seeing the big picture, demands [a] moderate position. Prescription opioids are both dangerous and beneficial, which means they'll always present a genuine moral dilemma.²⁷⁸

According to Rieder's logic, regulatory design for products that may help or harm ought to consider the welfare of different subpopulations. Nonetheless, this paper contends that youth be the primary consideration of tobacco control regimes.²⁷⁹

²⁷³ See Liza Gross, *Smoke Screen: Big Vape is Copying Big Tobacco's Playbook*, VERGE (Nov. 16, 2017, 9:00 AM), <https://www.theverge.com/2017/11/16/16658358/vape-lobby-vaping-health-risks-nicotine-big-tobacco-marketing>. Vaping Post published a divisive response. See Fergus Mason, *The Big Vape Lobby Strikes Again*, VAPING POST (Nov. 28, 2017), <https://www.vapingpost.com/2017/11/28/the-big-vape-lobby-strikes-again> ("Gross goes on to demonize nicotine... Put bluntly, Gross is talking nonsense. Her article is a grotesquely warped propaganda screed, which repeats debunked claims and dismisses or smears more objective research.").

²⁷⁴ See Ben Tobin, *E-Cigarette Company Juul Boosts Lobbying Spending by 167 Percent Amid FDA Scrutiny*, USA TODAY (Oct. 24, 2018, 4:36 PM), <https://www.usatoday.com/story/money/2018/10/24/juul-e-cigarette-company-increases-lobbying-spending-167-percent/1748382002>; Sheila Kaplan, *In Washington, Juul Vows to Curb Youth Vaping. Its Lobbying in States Runs Counter to that Pledge*, N.Y. TIMES (Apr. 28, 2019), <https://www.nytimes.com/2019/04/28/health/juul-lobbying-states-ecigarettes.html>; Francisco Alvarado, *Vape Store Owners are Freaking Out About Trump's Ban*, VICE (Sept. 13, 2019, 1:30 PM), https://www.vice.com/en_us/article/59nddd/where-will-people-buy-vapes-after-trumps-e-cig-ban.

²⁷⁵ Matthew L. Myers, *Evidence, Policy, and E-Cigarettes*, 375 NEW ENG. J. MED., at e6(1), e6(1) (2016) ("It is not by any definition 'absolutist' to call for FDA regulation of e-cigarettes. Effective regulation by the FDA is critical to minimizing the risks posed by e-cigarettes and maximizing the potential benefits.").

²⁷⁶ See *supra* Section II.A for analysis of e-cigarettes' harms, which are not shared by traditional nicotine-replacement therapy.

²⁷⁷ Travis N. Rieder, *There's Never Just One Side to the Story: Why America Must Stop Swinging the Opioid Pendulum*, 8 NARRATIVE INQUIRY IN BIOETHICS 225, 230 (2018).

²⁷⁸ *Id.* at 230–31.

²⁷⁹ Rieder argues for a "moderate" position, *id.* at 230, although it is not clear whether the mere existence of evidence on two sides of an issue means that public health is maximized in the middle. The more reserved conclusion is that the welfare of multiple subpopulations must be

2. *Why Youth Are the Primary Focus of Tobacco Regulatory Regimes*

In the 1990s, a startling revelation arose from tobacco research that would fundamentally change tobacco regulatory efforts.²⁸⁰ It helped encourage FDA Commissioner David Kessler to begin a years-long investigation of tobacco companies, and eventually to declare jurisdictional authority over cigarettes and issue health-promoting tobacco regulations²⁸¹—later overturned by *FDA v. Brown & Williamson Tobacco Corp.*²⁸² What permanently changed tobacco control efforts was the revelation that most smoking starts with children.²⁸³

The statistics speak for themselves. Updated data from the 2010 National Survey on Drug Use and Health reveals the ages at which people first tried cigarettes and became daily smokers:

Age	First use of a cigarette	Daily smokers: First use of a cigarette	Age of becoming a daily smoker
≤ 15	49.8%	58.5%	28.1%
≤ 18	81.5%	88.2%	65.1%
≤ 21	92.9%	95.9%	85.6%
≤ 26	98.0%	99.0%	96.2%
Mean Age	15.9	15.1	17.9

Table 3: Age of first trying cigarettes and becoming a daily smoker.²⁸⁴

Notably, about 90% of people who became daily smokers first tried cigarettes under age 18, and about two-thirds of them became daily smokers by age 18. Cigarette initiation is a problem primarily affecting youth. The statistics become even more extreme for people under 26. A full 99% of daily smokers had their first cigarette under the age of 26, and 96.2% of daily smokers began smoking daily by age

considered. As an example, imagine a newly approved drug that is found to kill 10% of people who take it. Some survivors may believe the drug mitigated their disease. It is difficult to argue in this scenario against FDA withdrawing approval of the medication.

²⁸⁰ See OFFICE OF THE SURGEON GEN., PREVENTING TOBACCO USE AMONG YOUTH AND YOUNG ADULTS: A REPORT OF THE SURGEON GENERAL 4–5 (2012) [hereinafter 2012 REPORT], https://www.ncbi.nlm.nih.gov/books/NBK99237/pdf/Bookshelf_NBK99237.pdf.

²⁸¹ See Margaret Gilhooley, *Tobacco Unregulated: Why the FDA Failed, and What to Do Now*, 111 YALE L.J. 1179, 1183–85 (2002) (reviewing KESSLER, *supra* note 148).

²⁸² 529 U.S. 120 (2000).

²⁸³ 2012 REPORT, *supra* note 280, at 134 (“One of the most important—and widely cited—findings from the 1994 Surgeon General’s report on smoking and health was that virtually all cigarette smoking begins before adulthood.”).

²⁸⁴ *Id.* at 136.

26. As Congress and the D.C. Circuit have articulated, tobacco use by children is “a pediatric disease of considerable proportions”²⁸⁵ This revelation offers a striking response to the argument that regulation should yield in favor of the right to “choose” to use tobacco products.

3. *Freedom-of-Choice Arguments Are Weak in the Youth Context*

The most potent defense of tobacco products for decades has been the freedom to choose to smoke, exemplified by the film *Thank You for Smoking*.²⁸⁶ The film features tobacco lobbyist Nick Naylor (played by Aaron Eckhart) having a mock debate with his son about what flavor is best, chocolate or vanilla. Little son Joey says definitely chocolate. (Well done, little Joey.) But rather than argue for vanilla, Nick Naylor adds another dimension: He defends “freedom and choice when it comes to our ice cream” because “that is the definition of liberty.” In other words, the merits can be disregarded because there is the superseding value of choice.²⁸⁷ (Figure 4).

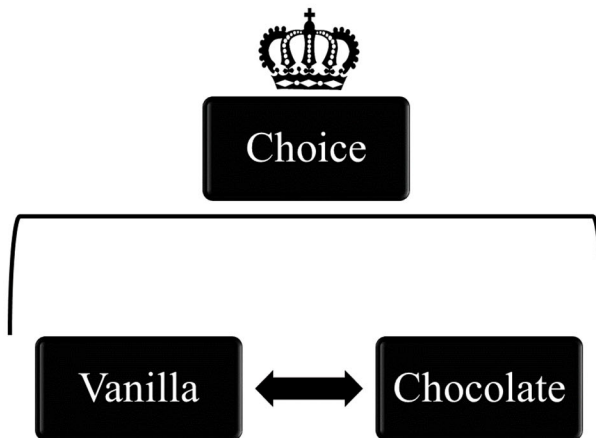


Figure 4: Freedom of choice is considered more important than the relative value of any particular flavor (even though chocolate is definitely better).

²⁸⁵ See *Nicopure Labs, LLC v. FDA*, 944 F.3d 267, 271 (D.C. Cir. 2019).

²⁸⁶ *THANK YOU FOR SMOKING* (Fox Searchlight Pictures 2006).

²⁸⁷ The Supreme Court echoed the supremacy of choice in two separate holdings within *National Federation of Independent Business v. Sebelius*, 567 U.S. 519 (2012). See *id.* at 568 (“[T]he shared responsibility payment [for violating the individual mandate] merely imposes a tax citizens may lawfully choose to pay in lieu of buying health insurance.”); *id.* at 588 (“Congress may offer the States grants and require the States to comply with accompanying conditions, but the States must have a genuine choice whether to accept the offer.”).

Freedom-of-choice rhetoric has played a key role in the persistence of tobacco addiction in the United States.²⁸⁸ It rose to prominence in industry defense of tobacco starting in 1977, and became the dominant argument to forestall regulation by the mid-1980s.²⁸⁹ Freedom of choice represents one “frame,” or a conceptual perspective familiar to listeners, that guides conversations and influences policymakers.²⁹⁰ Scholars such as Professor Jon Hanson have labeled choice rhetoric in the context of tobacco as a “blame frame” that justifies inequality and prevents meaningful response.²⁹¹ He names such choice rhetoric “choicism,” which involves the disparagement of victims through stigmatization of purported “choices” and attributes harms to the “preferences and character of individuals and their groups.”²⁹² For example, he notes the relative lack of sympathy and research money for lung cancer victims, who are often blamed for “choosing” to smoke.²⁹³ Lung cancer is the top-killing cancer (32% of cancer deaths), killing three times more people than either breast cancer or colorectal cancer, yet it receives only 10% of cancer research funding.²⁹⁴ Given lung cancer’s sheer prevalence and contribution to American mortality, one must ask whether the actions of other parties may be considered beyond the individual, such as the known aggressive marketing and lobbying of tobacco companies.²⁹⁵ Freedom of choice threatens regulation because many people conceive of it as a superseding value, even a right, above all possible policy options (chocolate

²⁸⁸ See Lissy C. Friedman, Andrew Cheyne, Daniel Givelber, Mark A. Gottlieb & Richard A. Daynard, *Tobacco Industry Use of Personal Responsibility Rhetoric in Public Relations and Litigation: Disguising Freedom to Blame as Freedom of Choice*, 105 AM. J. PUB. HEALTH 250, 251 (2015).

²⁸⁹ Pamela Mejia, Lori Dorfman, Andrew Cheyne, Laura Nixon, Lissy Friedman, Mark Gottlieb & Richard Daynard, *The Origins of Personal Responsibility Rhetoric in News Coverage of the Tobacco Industry*, 104 AM. J. PUB. HEALTH 1048, 1048 (2014).

²⁹⁰ *Id.*

²⁹¹ Jon Hanson & Kathleen Hanson, *The Blame Frame: Justifying (Racial) Injustice in America*, 41 HARV. C.R.-C.L. L. REV. 413, 417 (2006).

²⁹² *Id.*

²⁹³ *Id.* at 455.

²⁹⁴ See Ashley J. R. Carter & Cecine N. Nguyen, *A Comparison of Cancer Burden and Research Spending Reveals Discrepancies in the Distribution of Research Funding*, BMC PUB. HEALTH 526, 530–31 (2012); Rebecca L. Siegel, Kimberly D. Miller & Ahmedin Jemal, *Cancer Statistics, 2019*, 69 CA CANCER J. CLINICIANS 7, 9 (2019).

²⁹⁵ See 2012 REPORT, *supra* note 280.

or vanilla).²⁹⁶ Tobacco experts have gone to great lengths to produce counter-scholarship critiquing freedom of choice as an excuse for tobacco-related harms²⁹⁷ and have even argued there is no constitutionally protected liberty interest in smoking or vaping, as rhetoric often suggests.²⁹⁸ In the latest flurry of resistance to e-cigarette regulation, freedom of choice and rights-based rhetoric have come to the fore.²⁹⁹ (Figure 5).

²⁹⁶ See, e.g., Paul Brandmire, *Yes, Smoking Is Bad; but It's a Choice for Adults*, SC TIMES (Nov. 22, 2017, 9:02 PM), <https://www.sctimes.com/story/opinion/2017/11/22/yes-smoking-bad-choice-adults/107862398> (“I find [smoking] a dirty and disgusting habit. . . . But I hate the loss of individual freedom and personal responsibility more.”); Andrew Cheyne, Lori Dorfman, Richard A. Daynard, Pamela Mejia & Mark Gottlieb, *The Debate on Regulating Menthol Cigarettes: Closing a Dangerous Loophole vs Freedom of Choice*, 104 AM. J. PUB. HEALTH, at e54, e56–57 (2014) (quoting Niger Innis, Opinion, *When Good Intentions Have Disastrous Effects*, PHILADELPHIA TRIBUNE (Dec. 14, 2010) (“[G]overnment efforts to demonize menthol flavored cigarettes will inevitably lead to adding . . . another government imposed prohibition on a legal activity, hence another government restriction on people’s ability to exercise their liberty.”); Keith Barnhart, *Smoking Ban Violates Adults’ Freedom of Choice*, HERALD-DISPATCH (Feb. 21, 2010), https://www.herald-dispatch.com/opinion/keith-barnhart-smoking-ban-violates-adults-freedom-of-choice/article_66ed8151-3dde-5b0e-a35d-f552ba3ab3fc.html (“This ban [on smoking in bars and video parlors] will NOT cause anyone to quit smoking. The issue here is choice and why it has been taken away from us. Adults are entitled to freedom of choice.”).

²⁹⁷ See, e.g., Mejia et al., *supra* note 289, at 1050 (“This framing of smoking as a consumer choice ignores tobacco addiction, implying that a consumer is capable of a truly free choice—and consequently, that smokers . . . , not the industry, are responsible for the health consequences.”); Hanson & Hanson, *supra* note 291, at 445; Friedman et al., *supra* note 288; cf. Allan M. Brandt, *Inventing Conflicts of Interest: A History of Tobacco Industry Tactics*, 102 AM. J. PUB. HEALTH 63, 64 (2012) (describing tobacco companies’ determination to define the social meaning of tobacco).

²⁹⁸ See Samantha K. Graff, *There is No Constitutional Right to Smoke: 2008*, TOBACCO CONTROL LEGAL CONSORTIUM, Mar. 2008, at 1; Hudson B. Kingston, *There is No Constitutional Right to Smoke or Toke*, TOBACCO CONTROL LEGAL CONSORTIUM, Jan. 2019, at 5.

²⁹⁹ See, e.g., Leah Sottile, *The Right to Vape*, ATLANTIC (Oct. 8, 2014), <https://www.theatlantic.com/health/archive/2014/10/the-right-to-vape/381145> (noting vaping, for some, has become “a lifestyle, a brotherhood, a community, a movement fighting for a ‘right to vape’”); Tommy Drorbaugh, *Opinion: E-Cigarette Resolution Attempts to Control Students Freedom of Choice*, ARBITER (Mar. 19, 2019), <https://arbiteronline.com/opinion-e-cigarette-resolution-attempts-to-control-students-freedom-of-choice> (“Although smoking and vaping can adversely affect your health, so can a plethora of other substances that are legal to consume by adults in the United States. But, a responsible adult should be able to make their own decisions when it comes to their bodies.”); Brian Darling, *The FDA Is Overreaching with its Attempt to Ban Vaping*, OBSERVER (Jan. 28, 2019, 12:33 PM), <https://observer.com/2019/01/fda-overreaches-vaping-ban/> (“Adults should have the freedom to choose vaping, because it is a safe alternative to smoking cigarettes.”).

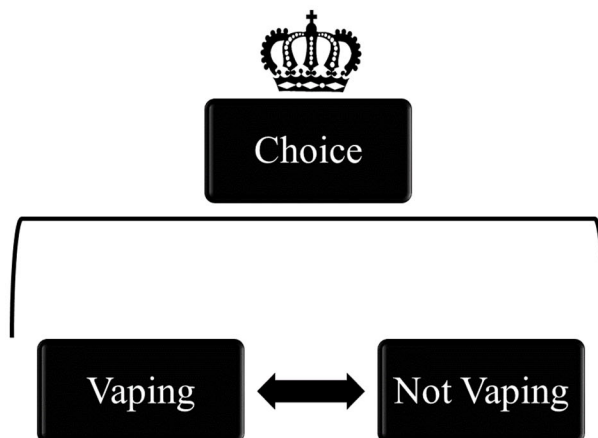


Figure 5: Freedom of choice has been argued as more important than whether a particular person vapes or not, regardless of the resulting harm.

However, using e-cigarettes is a more significant outcome than consuming chocolate or vanilla ice cream. If chocolate ice cream caused more cancer or heart attacks than vanilla, there would be a strong argument for the government to intervene. Viewing e-cigarettes as a matter of choice presents a false equivocation between two extremely different outcomes. Further, when we add an assumption that chocolate ice cream is exceptionally addictive, the user is left without meaningful choice. Quitting smoking is notoriously difficult.³⁰⁰ And why would we entrust such an important “choice” to teenagers?

Freedom-of-choice arguments become weaker on learning that most tobacco use begins under age 18.³⁰¹ It is well accepted that youth do not possess the same levels of self-control, knowledge about the world, or maturity to act in their best interest. Arguably, the reason that most tobacco use starts before age 18 (and especially before age 26) is a fundamentally human and biological lack of brain maturity (and exploitation thereof).³⁰²

The brain continues developing throughout adolescence and into the 20s, new research has strongly indicated.³⁰³ During the teenage years and beyond, there are

³⁰⁰ *What You Need to Know to Quit Smoking*, TRUTH INITIATIVE (Nov. 7, 2018), <https://truthinitiative.org/research-resources/quit-smoking-vaping/what-you-need-know-quit-smoking>.

³⁰¹ See *supra* Section II.B.2.

³⁰² See *supra* Section II.B.6.

³⁰³ See Susan M. Sawyer, Peter S. Azzopardi, Dakshitha Wickremarathne & George C. Patton, *The Age of Adolescence*, 2 LANCET CHILD & ADOLESCENT HEALTH 223, 224 (2018); CLEA MCNEELY & JAYNE BLANCHARD, JOHNS HOPKINS BLOOMBERG SCH. OF PUB. HEALTH, THE

three important brain changes worth highlighting. The first is resistance to peer pressure, which has a critical learning period between the ages 14 and 18.³⁰⁴ However, this resistance continues to be developed into college years and beyond.³⁰⁵ The second change is development of the pre-frontal cortex, which is responsible for higher-order thinking, planning, and impulse inhibition; the pre-frontal cortex is only half-developed by age 18.³⁰⁶ Third, the brain's reward system accelerates in the teenage years and reaches an adult level around age 25.³⁰⁷

Brain development is important to consider in policymaking. As one physician professor argues:

An expanded and more inclusive definition of adolescence is essential for developmentally appropriate framing of laws, social policies, and service systems. Rather than age 10–19 years, a definition of 10–24 years corresponds more closely to adolescent growth and popular understandings of this life phase and would facilitate extended investments across a broader range of settings.³⁰⁸

When considering e-cigarette regulations, it is important to remember that youth, even beyond age 18, are impressionable. Psychological research has found that youth, faced with internal conflicts about their identities, look to external cues to define themselves, such as evocative images in tobacco advertisements.³⁰⁹ Numerous studies have found that brief exposures of adolescents to e-cigarette advertisements greatly increase desire to purchase e-cigarettes.³¹⁰ Tobacco advertisements often show models depicting sophistication and independence, qualities appealing to

TEEN YEARS EXPLAINED: A GUIDE TO HEALTHY ADOLESCENT DEVELOPMENT 22 (2009), https://www.jhsph.edu/research/centers-and-institutes/center-for-adolescent-health/_docs/TTYE-Guide.pdf (“The brain changes continue up to at least age 21, and some scientists believe maturation is not complete until 25.”); *Tell Me More: Brain Maturity Extends Well Beyond Teen Years*, NPR (Oct. 10, 2011, 12:00 PM), <https://www.npr.org/templates/story/story.php?storyId=141164708>.

³⁰⁴ See Laurence Steinberg & Kathryn C. Monahan, *Age Differences in Resistance to Peer Influence*, 43 DEVELOPMENTAL PSYCHOL. 1531, 1531 (2007).

³⁰⁵ *Id.*

³⁰⁶ *Tell Me More*, *supra* note 303.

³⁰⁷ *Id.*

³⁰⁸ Sawyer et al., *supra* note 303, at 223.

³⁰⁹ See William G. Shadel, Shannah Tharp-Taylor & Craig S. Fryer, *Exposure to Cigarette Advertising and Adolescents' Intentions to Smoke: The Moderating Role of the Developing Self-Concept*, 33 J. PEDIATRIC PSYCHOL. 751, 752 (2008).

³¹⁰ 2016 REPORT, *supra* note 12, at 169–71.

adolescents.³¹¹ Tobacco companies paint their products as “a rite of passage to adulthood.”³¹² Therefore, regulation is particularly justified to prevent the wide-scale addiction of youth, a population inherently susceptible in an unregulated market.

4. *Tobacco Companies Know that Youth Are an Essential Demographic Target*

Tobacco companies, being savvy marketers, were the first to realize the importance of targeting youth.³¹³ Tobacco companies know that youth are impressionable, are the tobacco initiators within American society, and represent the next generation of adult smokers. Tobacco industry documents have proven this knowledge. For example, a 1981 report from Philip Morris (known today as Altria) said:

Today’s teenager is tomorrow’s potential regular customer, and the overwhelming majority of smokers first begin to smoke while still in their teens. . . . The smoking patterns of teenagers are particularly important to Philip Morris.³¹⁴

Similarly, a 1978 Lorillard Tobacco Company memo communicated: “The base of our business is the high school student.”³¹⁵ And an R. J. Reynolds Tobacco Company report from 1984 stated:

Younger adult smokers have been the critical factor in the growth and decline of every major brand and company over the last 50 years. . . . The renewal of the market stems almost entirely from 18-year-old smokers. No more than 5% of smokers start after age 24.³¹⁶

The internal documents of tobacco companies speak for themselves: Youth are an integral target of the tobacco industry.³¹⁷

³¹¹ COMM. ON PREVENTING NICOTINE ADDICTION IN CHILDREN AND YOUTHS, GROWING UP TOBACCO FREE: PREVENTING NICOTINE ADDICTION IN CHILDREN AND YOUTHS 120 (Barbara S. Lynch & Richard J. Bonnie eds., 1994).

³¹² *Id.*

³¹³ See Jaimee Coombs, Laura Bond, Victoria Van & Mike Daube, “*Below the Line*”: *The Tobacco Industry and Youth Smoking*, 4 AUSTRALIAN MED. J. 655, 669 (2011) (“The documents [herein cited] provide evidence that the industry invested great time and resources in developing strategies to attract youth.”); *Tobacco and Youth*, WORLD HEALTH ORG., <https://web.archive.org/web/20180327022322/http://www.who.int/tobacco/control/populations/youth/en/> (last visited July 29, 2021).

³¹⁴ LAURA BACH, CAMPAIGN FOR TOBACCO-FREE KIDS, TOBACCO COMPANY MARKETING TO KIDS 1 (2020), <https://www.tobaccofreekids.org/assets/factsheets/0008.pdf>.

³¹⁵ *Id.* at 2.

³¹⁶ Cheryl L. Perry, *The Tobacco Industry and Underage Youth Smoking: Tobacco Industry Documents from the Minnesota Litigation*, 153 ARCHIVES PEDIATRIC & ADOLESCENT MED. 935, 936 (1999).

³¹⁷ *Id.* at 935 (“Youths are critical to the tobacco companies. . . . [E]arly through middle adolescence is the developmental stage during which smoking onset occurs.”).

5. *E-Cigarette Companies Know that Youth Are an Essential Demographic Target*

The e-cigarette's popularity among youth was no market accident. Substantial research has shown that e-cigarette companies have not only marketed to vulnerable groups,³¹⁸ but to youth.³¹⁹ While the Master Settlement Agreement barred participating cigarette companies from advertising to youth,³²⁰ e-cigarette companies have not respected the spirit of this provision.

Professor Robert Jackler's team examined the first three years of Juul's advertising.³²¹ Juul's innovation in advertising tobacco lies in enlisting young people with large social media followings ("influencers") to post alluring Juul images and videos. He writes:

[D]uring the phenomenal upswing in demand over 2015 to 2018 JUUL continued to engage in advertising either targeted to youth (initial year) or by placing its promotional material preferentially in youth consumed media channels (later 2 years). During its meteoric growth, JUUL posted a prodigious volume of advertisements via social media, promoted them via paid influencers, and distributed its messages to a wide community via hashtags.³²²

An example of the glamorous, sexualized, youth-targeted advertisement analyzed by Professor Jackler is below. (**Figure 6**).

³¹⁸ See *supra* Section II.A.7.

³¹⁹ Robert K. Jackler, Cindy Chau, Brook D. Getachew, Mackenzie M. Whitcomb, Jeffrey Lee-Heidenreich, Alexander M. Bhatt, Sophia H.S. Kim-O'Sullivan, Zachary A. Hoffman, Laurie M. Jackler & Divya Ramamurthi, *JUUL Advertising over Its First Three Years on the Market*, STANFORD RESEARCH INTO THE IMPACT OF TOBACCO ADVERTISING (SRITA) (Jan. 31, 2019); see 2016 REPORT, *supra* note 12, at 5 ("E-cigarettes are marketed by promoting flavors and using a wide variety of media channels and approaches that have been used in the past for marketing conventional tobacco products to youth and young adults."); *E-Cigarette Ads and Youth*, CTRS. FOR DISEASE CONTROL & PREVENTION, <https://www.cdc.gov/vitalsigns/ecigarette-ads/index.html> (last updated Mar. 23, 2017) ("More than 18 million (7 in 10) US middle and high school youth were exposed to e-cigarette ads in 2014.").

³²⁰ See *Master Settlement Agreement*, PUB. HEALTH LAW CTR. (1998), <https://publichealthlawcenter.org/sites/default/files/resources/master-settlement-agreement.pdf>.

³²¹ Jackler et al., *supra* note 319, at 1.

³²² *Id.* at 39.

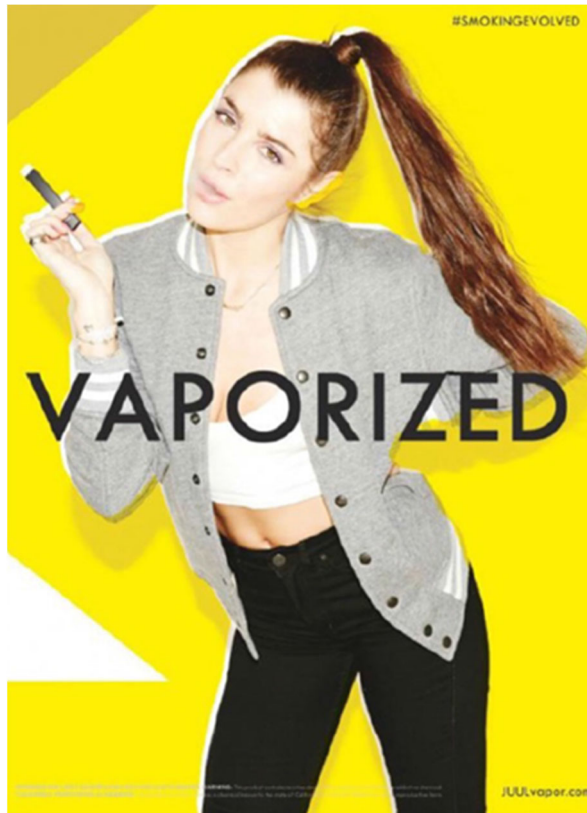


Figure 6: Sexualized youth appearing in a Juul advertisement.³²³

Juul also ran a youth education program in 2018.³²⁴ It paid schools \$10,000 each in exchange for allowing Juul to educate youth purportedly about the danger of tobacco addiction.³²⁵ At a federal congressional hearing, 17-year-old Caleb Mintz testified that a Juul representative came to his school when he was in ninth grade and told him and classmates how to use a Juul e-cigarette, instructed that the product was “totally safe,” and told students Juul does not want them as customers.³²⁶ It is unclear why knowing how to use a Juul e-cigarette comports with the goal of

³²³ *Id.* at 28.

³²⁴ Kenrick Cai, *Juul Funded High Schools, Recruited Social Media Influencers to Reach Youth, House Panel Charges*, FORBES (July 25, 2019, 9:50 PM), <https://www.forbes.com/sites/kenrickcai/2019/07/25/juul-high-schools-influencers-reach-youth-house-investigation/#21c70fe633e2>.

³²⁵ *Id.*

³²⁶ See *Examining JUUL’s Role in the Youth Nicotine Epidemic: Part I: Hearing Before the Subcomm. on Economic & Consumer Policy of the H. Comm. on Oversight & Reform*, 116th Cong. (2019) (statement of Caleb Mintz, high-school student), <https://oversight.house.gov/legislation/hearings/examining-juul-s-role-in-the-youth-nicotine-epidemic-part-i>.

preventing youth tobacco addiction, nor does using what appears to be reverse psychology. Only six schools used the program before it was scrapped due to public criticism.³²⁷ The program is consistent with Dr. Jackler's conclusion that Juul knew that youth were an important marketing target.

In probably its most egregious violations, Juul appears to have purchased ads on Cartoon Network and Nickelodeon, as well as ads in Seventeen Magazine and educational websites dedicated to middle- and high-school students.³²⁸ Given the importance of youth to the tobacco industry, it is unsurprising, but still upsetting, that Juul marketed to youth.

As scrutiny of Juul has increased and FDA's limited flavor ban has reduced availability of youth-appealing flavors, companies, such as the maker of Puff Bars, have begun marketing inexpensive, youth-appealing e-cigarettes that circumvent the ban.³²⁹ (Figure 7). Puff Bars are sleek, disposable e-cigarettes marketed with bright colors and youth-appealing flavors such as O.M.G. (orange-mango-guava).³³⁰ Puff Bars have been the subject of numerous viral videos on TikTok with tens of millions of views, although researchers have not determined the company's responsibility for these videos.³³¹ Both Puff Bars and Juul are popular brands among youth, with Juul being the most popular.³³² It is doubtful that the maker of Puff Bars failed to recognize that youth were a lucrative and important target.

³²⁷ Cai, *supra* note 324.

³²⁸ Sheila Kaplan, *Juul Bought Ads Appearing on Cartoon Network and Other Youth Sites, Suit Claims*, N.Y. TIMES (Feb. 12, 2020), <https://www.nytimes.com/2020/02/12/health/juul-vaping-lawsuit.html>.

³²⁹ See *supra* notes 151–55 and accompanying text.

³³⁰ See *What Are Puff Bars?*, TRUTH INITIATIVE (Jan. 31, 2020), <https://truthinitiative.org/research-resources/emerging-tobacco-products/what-are-puff-bars>.

³³¹ See Andy S.L. Tan & Erica Weinreich, *#PuffBar: How Do Top Videos on TikTok Portray Puff Bars?*, TOBACCO CONTROL, Sept. 15, 2020, at 1.

³³² Teresa W. Wang, Andrea S. Gentzke, Linda J. Neff, Emily V. Glidden, Ahmed Jamal, Eunice Park-Lee, Chunfeng Ren, Karen A. Cullen, Brian A. King & Karen A. Hacker, *Characteristics of E-Cigarette Use Behaviors Among US Youth, 2020*, JAMA NETWORK OPEN, June 1, 2021, at 1, 6.



Figure 7: Puff Bars.³³³ They have been formally removed from the U.S. market, although there remains some availability.³³⁴

6. *Youth Are the Battleground*

Youth are impressionable. Youth are targeted by tobacco companies. And it is during youth that most tobacco use begins.

The adults of today were once youth. Their addiction by and large originates from when they were under 18. If people “choose” to smoke, it is unclear why it is assumed they possessed full faculties below the age of 18. Given that nicotine is one of the most addictive substances identified in history,³³⁵ most American tobacco users have little agency in their long-held addictions. About 70% of smokers say they wish to quit, yet only 7% of smokers quit each year, and many relapse.³³⁶

It is clear that tobacco use, fundamentally, is a youth problem. From an industry perspective, there is no long-term future in the marketing of tobacco if youth do not partake.³³⁷ From a public health perspective, preventing youth initiation of tobacco is 95% of tobacco control. Many tobacco commentators miss the importance of this problem, and believe health officials are merely trying to protect kids because they are sympathetic. While kids are indeed sympathetic, health officials and tobacco companies are aware that kids are the future of tobacco. The continuing epidemic of tobacco addiction in the United States depends largely on whether today’s

³³³ PUFF, *supra* note 153.

³³⁴ *Puff Bar Suspends Sales in the United States*, TOBACCO REP. (July 14, 2020), <https://tobaccoreporter.com/2020/07/14/puff-bar-suspends-u-s-sales>.

³³⁵ Deeming Rule, *supra* note 7, at 28,988 (“Nicotine is one of the most addictive substances used by humans.” (internal citation omitted)); see also Thomas C. Schelling, *Addictive Drugs: The Cigarette Experience*, 255 SCI. 430, 431 (1992) (“Cigarettes are extremely addictive. Most users are addicted; few who have smoked regularly for a year or more find it easy to quit.”); Andrew McIvor, *Tobacco Control and Nicotine Addiction in Canada: Current Trends, Management and Challenges*, 16 CANADIAN RESPIRATORY J. 21, 22 (2009).

³³⁶ *What You Need to Know*, *supra* note 300.

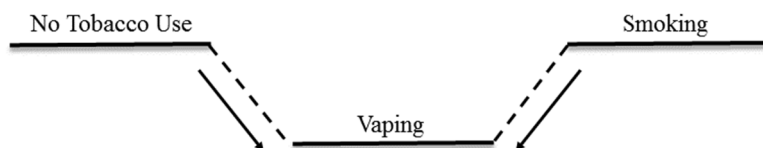
³³⁷ See Perry, *supra* note 316, at 935.

kids adopt tobacco products. Sure enough, the ten-year history of e-cigarettes in the United States has largely been a discussion about kids. Of course, tobacco companies would never admit publicly their desire to market to kids, and instead their arguments have revolved around protecting adults' rights.

7. *Putting It All Together: Intergenerational Analysis*

E-cigarettes present a more complicated picture than traditional cigarettes because they offer a potential benefit to current cigarette users. While cigarettes should arguably not exist in society, e-cigarettes potentially have a legitimate function for people who use cigarettes and wish to transition.

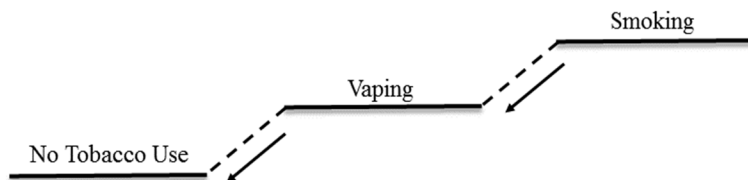
Unfortunately, a small number of vocal adults partaking in the vaping advocacy movement, spurred by industry groups, have argued for their freedom to vape free of any restrictions.³³⁸ To the extent these adults resist all regulation of vaping, they have arguably become unwitting allies of tobacco companies in seeking a world unfavorable to children's health. The conceptual understanding that all barriers to vaping must be minimized to benefit smokers is demonstrated below, with traveling downhill representing an easier transition. It is apparent that vaping is the likely outcome of such a regime.



Model 1: Minimizing all barriers to e-cigarettes.

There is strong evidence to support a more nuanced perspective, one that explicitly creates a role for regulation in protecting youth. There is a fair contention that states and localities should preserve limited ability to vape tobacco-flavored e-cigarettes, but subject to restrictions. Children are attracted to flavored products, low prices, easy availability, and eye-catching marketing—which can be addressed while leaving e-cigarettes on the market for people who wish to transition. The outcome of such a regulatory regime is demonstrated below.

³³⁸ Rachel Bluth & Lauren Weber, 'We Vape, We Vote': *How Vaping Crackdowns Are Politicizing Vapers*, KAISER HEALTH NEWS (Oct. 10, 2019), <https://khn.org/news/we-vape-we-vote-how-vaping-crackdowns-are-politicizing-vapers>.



Model 2: Allow some access to e-cigarettes, subject to restrictions that make “no tobacco use” the default and easiest option.

The second model allows for e-cigarettes to serve as harm reduction, that is, an intermediate step toward no tobacco use. E-cigarettes must not be so attractive and accessible as to draw in people who would otherwise not have used tobacco. If they do, e-cigarettes cease to constitute harm reduction.

Given the importance of intergenerational equity, youth can and should be protected from vaping, while adults should retain access to e-cigarettes subject to regulation, as long as it is consistent with public health as required by the Tobacco Control Act. The importance of intergenerational equity features heavily in the solutions discussed later in this paper.³³⁹

C. *The Intent to Addict and Policy Implications*

As discussed,³⁴⁰ Juul demonstrated its intent to addict youth by marketing directly to them through social media and through ad placements on youth-oriented services like Cartoon Network and Nickelodeon. But Juul is likely not the only e-cigarette company marketing to kids, directly or indirectly. Collectively, e-cigarette companies have released more than 7000 flavors,³⁴¹ many of which appear to be directed at children, such as cherry, strawberry, gummy bear, chocolate, and cinnamon.³⁴² Further, e-cigarette manufacturers have been increasing their products’ nicotine concentrations,³⁴³ and, as noted, nicotine is more addicting to youth.³⁴⁴ These

³³⁹ See *infra* Part IV.

³⁴⁰ See *supra* Section II.B.5.

³⁴¹ Shu-Hong Zhu, Jessica Y. Sun, Erika Bonnevie, Sharon E. Cummins, Anthony Gamst, Lu Yin & Madeline Lee, *Four Hundred and Sixty Brands of E-Cigarettes and Counting: Implications for Product Regulation*, 23 TOBACCO CONTROL, at iii3, iii5 (2014).

³⁴² See M.B. Harrell, S.R. Weaver, A. Loukas, M. Creamer, C.N. Marti, C.D. Jackson, J.W. Heath, P. Nayak, C.I. Perry, T.F. Pechacek & M.P. Eriksen, *Flavored E-Cigarette Use: Characterizing Youth, Young Adult, and Adult Users*, 5 PREVENTIVE MED. REPS. 33, 34 (2017).

³⁴³ Robert K. Jackler & Divya Ramamurthi, *Nicotine Arms Race: JUUL and the High-Nicotine Product Market*, 28 TOBACCO CONTROL 623, 623 (2019).

³⁴⁴ See *supra* Section II.A.6.

concerns are not only theoretical, but actually reflected in data showing that youth use of e-cigarettes far outpaces adult use.³⁴⁵

While the “intent to addict” is clear from research and journalism, it is less clear how it should be used in regulatory policy. On the one hand, intentional conduct is the most blameworthy of all, as reflected by more stringent penalties across criminal and tort law. On the other hand, one might argue that the action of blaming may lead to more tort interventions and ex post responses, rather than much needed ex ante regulation of addicting products. Treating nicotine addiction post hoc is far more challenging than preventing it ex ante.

One resolution to this dilemma is to ask why companies intend for people to become addicted to e-cigarettes, combustible tobacco, opioids, and other addicting products. E-cigarettes arguably represented a “race to the bottom.” Juul tore open the market with nicotine salts (better absorbed and smoother to inhale)³⁴⁶ at a historically high 5% concentration—prior e-cigarettes offered concentrations averaging 2% and capping at 3%.³⁴⁷ Juul targeted its products to youth for financial reasons.³⁴⁸ Similarly, successful combustible cigarette companies were known to modulate the pH of cigarettes in order to increase nicotine absorption and thereby make their cigarettes more addicting.³⁴⁹ They also marketed extensively to youth.³⁵⁰

*It is this paper’s suggestion that intention to addict is a naturally arising phenomenon from markets in which the most addicting product takes over by a quasi-evolutionary process.*³⁵¹ While this principle is too broad to explore fully here, it is suggested that bad actors may be inevitable in the sale of addicting products. In a sea of addicting products, it is the most addicting and the most irresponsibly marketed products that will take hold. These bad actors may reduce the standards to which other companies are held; in the case of e-cigarettes, it was not long before other e-cigarette companies began selling at Juul’s high nicotine concentration. As written by Dr. Jackler and Divya Ramamurthi, “Juul has triggered a widespread rush among aerosol purveyors to market e-liquid in unprecedentedly high nicotine

³⁴⁵ See King et al., *supra* note 16, at 690; Vallone et al., *supra* note 20.

³⁴⁶ King et al., *supra* note 16, at 690.

³⁴⁷ Jackler & Ramamurthi, *supra* note 343, at 623.

³⁴⁸ See *supra* Section II.B.2 for an analysis on why youth are profitable targets for tobacco companies.

³⁴⁹ See Jackler & Ramamurthi, *supra* note 343, at 623.

³⁵⁰ For example, the famous “Joe Camel” campaign by R.J. Reynolds was most familiar to younger age groups; the 12- to 13-year-olds were the most aware. See Sonia A. Duffy & Dee Burton, *Cartoon Characters as Tobacco Warning Labels*, 154 ARCHIVES PEDIATRIC & ADOLESCENT MED. 1230, 1230–31 (2000).

³⁵¹ The evolution can be seen not just in rising nicotine concentrations and more absorbable formulations, but also in how initial e-cigarettes were intended to be similar to smoking, whereas newer models pushed for innovation, customizability, and exciting new flavors. See Zhu et al., *supra* note 341, at iii6.

concentrations.”³⁵² Rather than regulate this race to the bottom *ex ante*, the United States shifts most regulatory authority *ex post* (to litigation).³⁵³ It is no surprise, then, that we constantly have addiction on our hands. Solutions will be discussed in Part IV.³⁵⁴ The race to the bottom may be curable with pre-established safeguards for products with addictive potential, as well as strict liability to hold actors accountable. Products must not come to market outside of a regulatory regime, as e-cigarettes did.

III. TWO WORRIES

This paper has covered a large swath of arguments and information about e-cigarettes. Two themes—or worries—run throughout. Evidence for both claims are dispersed throughout the above text, although this paper cannot do full justice to these claims in the remaining space.

The first is that tobacco use and market power are engaged in a harmful cycle. The cycle begins with addiction. Addiction leads to market success. Market success leads to market power.³⁵⁵ Market power can be used to protect and expand the market. As an example, cigarettes have been sold for a century and a half, were denounced by the U.S. Surgeon General in the 1960s, finally came under U.S. federal regulation in 2009, and are still one of the leading causes of death in the United States, killing about 480,000 Americans each year.³⁵⁶ Such persistence would be impossible without major market power. That e-cigarette addiction among youth has risen almost every year for ten years suggests that market power may be at play in this new arena. A recent example was a Montana ballot measure that would have expanded Medicaid by raising taxes on tobacco products, including e-cigarettes; however, the tobacco force Altria spent \$17 million on a public relations campaign disparaging the measure, and it worked.³⁵⁷ The measure failed.³⁵⁸ Beyond manufac-

³⁵² See Jackler & Ramamurthi, *supra* note 343, at 623.

³⁵³ See Samuel Issacharoff, *Regulating After the Fact*, 56 DEPAUL L. REV. 375, 382 (2007).

³⁵⁴ See *infra* Part IV.

³⁵⁵ For example, as of 2014, five firms had 85% of global tobacco market share. See NAT'L CANCER INST., THE ECONOMICS OF TOBACCO AND TOBACCO CONTROL 455 (2016), https://cancercontrol.cancer.gov/brp/tcrb/monographs/21/docs/m21_complete.pdf.

³⁵⁶ See OFFICE OF THE SURGEON GEN., THE HEALTH CONSEQUENCES OF SMOKING—50 YEARS OF PROGRESS: A REPORT OF THE SURGEON GENERAL 11, 784 (2014), https://www.ncbi.nlm.nih.gov/books/NBK179276/pdf/Bookshelf_NBK179276.pdf.

³⁵⁷ See Sam Wilson, *Montana Voters Reject Paying for Medicaid Expansion with Tobacco Tax*, BILLINGS GAZETTE (Nov. 7, 2018), https://billingsgazette.com/news/state-and-regional/montana/montana-voters-reject-paying-for-medicaid-expansion-with-tobacco-tax/article_02cf2516-79b9-52de-bc2e-ad4f9b931a85.html.

³⁵⁸ *Id.*

turers, financial intermediaries, such as vape shops, convenience stores, and pharmacies, may become incidental allies as they benefit from sales. To avoid such a power accumulation, action in tobacco is best upfront, before market success and market power—and therefore before addiction.

The second worry is related: that action must be taken before addiction sets in because addiction makes policy, and policy makes addiction. That is, the sale of an addicting product makes it harder to set regulatory policy. For example, after President Trump proposed a ban on flavored e-cigarettes, a coalescing bloc of e-cigarette-using adults became vaping activists, largely under the label “We Vape We Vote.”³⁵⁹ Their most powerful argument was a vaping industry study showing that 83% of e-cigarette users in battleground states were single-issue voters on the issue of vaping.³⁶⁰ The movement succeeded in having several types of e-cigarettes exempted from the flavor ban.³⁶¹ People addicted to a product may often vote to deregulate the product; addiction, then, begets policy, and policy perpetuates addiction. The harms of e-cigarettes then fall most on youth, who have little political clout and no vote.

In sum, addiction may allow for the rise of concentrated market power and a dedicated voting bloc. These themes are worrisome, and they suggest that addiction is best managed through legal changes that regulate highly addicting products into carefully circumscribed uses.

IV. SOLUTIONS

Solutions fall into three categories: (1) general legal and regulatory problems; (2) e-cigarette-specific reforms; and (3) general changes to how addicting products are conceived and regulated.

A. General Legal and Regulatory Problems

When addicting products, such as e-cigarettes, are brought to market, time and preparation are of the essence. However, the manufacturer generally has “the lead” and therefore the advantage. E-cigarette companies have already amassed significant levels of resources and power, and are wielding it in national and state policymaking.

³⁵⁹ Richard Harris, *Politics, Industry Backlash Stall White House Ban on Flavored Vaping Products*, NPR (Nov. 18, 2019, 5:13 PM), <https://www.npr.org/sections/health-shots/2019/11/18/780562607/politics-industry-backlash-stall-white-house-ban-on-flavored-vaping-products>.

³⁶⁰ See Barbara Corbellini Duarte & Robin Lindsay, *As the FDA Cracks Down on E-Cigarettes, Vapers are Starting to Become One-Issue Voters*, BUS. INSIDER (Jan. 3, 2020, 12:20 PM), <https://www.businessinsider.com/vaping-flavors-ban-crackdown-voting-election-2020-1>.

³⁶¹ *Id.*

Looking backward, ex ante changes could have averted addiction and the associated concentration of market power.

First, regulatory statutes should be broadly based on addicting substances, and should not require additional steps to establish regulatory authority. For example, the Tobacco Control Act provided FDA jurisdiction over tobacco products, but required a rulemaking process to declare its authority over others beyond four named categories. This barrier impeded FDA e-cigarette regulation for seven years, which was long enough for a rapid rise in youth use. This problem may have been avoided if federal courts had allowed FDA to regulate e-cigarettes under its drug and device authorities, given that nicotine and e-cigarettes clearly fall into these categories (exemplified by nicotine gum constituting a drug). However, the unnecessarily harsh opinion in *Sottera, Inc. v. FDA* extended *FDA v. Brown & Williamson* far beyond its logical moorings and required FDA to regulate e-cigarettes solely under the Tobacco Control Act. Therefore, legislative and court decisions halted a rapid FDA response to e-cigarettes. This Article suggests that Congress and federal courts undermine public health regulations when they disempower FDA experts and omit the practical analysis of their own role in facilitating addiction. Congress ought to afford jurisdiction over the addicting substance itself, such as all nicotine-containing products, and consider additional jurisdiction over “addicting products” more generally.³⁶² Courts ought to be careful with formalism, which, though sometimes helpful, may lead to arbitrary decisions in cases where borderline products teeter on the edges of statutory text.

Second, multiple failures within the Executive Branch highlight important administrative law lessons. After the Deeming Rule in 2016, the Office of Management and Budget (OMB) and the White House, in conjunction with the e-cigarette industry, quashed two FDA flavor bans. Moreover, the 2016 Deeming Rule allowed unapproved e-cigarettes to remain on the market until 2019. After the change of administration that same year, newly appointed FDA Commissioner Scott Gottlieb postponed the due date for e-cigarette premarket applications to 2022,³⁶³ perhaps due to faith in the innovative function of e-cigarettes in helping smokers quit. This move granted Juul, introduced in 2015, essential time to flourish, using its higher nicotine concentration and its new “nicotine salt” formulation, which made its product more addicting.³⁶⁴ E-cigarettes pose a powerful counterpoise to agency accountability arguments. Advocates for agency accountability argue that administrative agencies possess too much unsupervised discretion.³⁶⁵ According to Professors

³⁶² See *infra* Section IV.C.

³⁶³ U.S. FOOD & DRUG ADMIN., *supra* note 108.

³⁶⁴ Huang et al., *supra* note 13, at 146; King et al., *supra* note 16 at 690.

³⁶⁵ See Cass R. Sunstein & Adrian Vermeule, *The Morality of Administrative Law*, 131 HARV. L. REV. 1924, 1928 (2018).

Cass Sunstein and Adrian Vermeule, such criticisms have reached a “fever pitch.”³⁶⁶ The normally proposed solution for insufficient accountability is granting greater presidential control over the agency.³⁶⁷ In the case of e-cigarettes, presidential control over FDA, mediated by OMB as well as the presidential appointment power, served as a barrier to e-cigarette regulation. That is, presidential power and related corporate influence obstructed an e-cigarette flavor ban and premarket review. This finding suggests not that accountability is unimportant, but that some forms of accountability may be better than others at arriving at expertise-based public health regulations. For example, Professor Gillian Metzger has suggested a greater emphasis on accountability to experts within an agency, to bureaucratic supervisors, and to the law.³⁶⁸ Although some presidential power over agencies has constitutional dimensions,³⁶⁹ courts ought not to be sanguine about positive effects of presidential control. Other forms of accountability might be less subject to corporate influence.³⁷⁰ For example, a federal court mandated that FDA expedite premarket review of e-cigarette products.³⁷¹

B. *E-Cigarette-Specific Reforms*

Even though addiction may be best managed *ex ante*, we are still “*ex ante*” to many youth becoming addicted. Therefore, regulatory changes could offer preventive benefits. This Part offers a sample, not a comprehensive list, of possible reforms.

First, FDA should expedite its review of e-cigarettes, which continue to be sold without public health review or approval. FDA provided too much leeway to e-cigarette manufacturers in the form of more than ten years of near-free-market sales. As discussed, FDA faced numerous situational impediments, but the agency could have done more. To the extent FDA’s arguable inaction in the e-cigarette space is due to lack of resources and personnel needed to erect a complex approval mechanism, FDA could be transparent with such barriers so that the public and policy-makers are aware. With regard to policy objectives, FDA should consider limiting the nicotine content of cigarettes and e-cigarettes to reduce their addictiveness. Reducing addictiveness would benefit both children and adults, whereas allowing increasingly concentrated e-cigarette products to enter the market with the goal of

³⁶⁶ *Id.*

³⁶⁷ See Stephanopoulos, *supra* note 150, at 1012; *Free Enter. Fund v. Pub. Co. Accounting Oversight Bd.*, 561 U.S. 477, 497–98 (2010) (asserting that presidential control over agency action is important to avoid diffusion of accountability, i.e., to ensure clarity on whom the public should blame for a harmful policy) (citations omitted).

³⁶⁸ Metzger, *supra* note 107, at 79–81.

³⁶⁹ *Id.* at 79.

³⁷⁰ See, e.g., *Motor Vehicle Mfrs. Ass’n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 56–57 (1983) (holding agency accountable to prior expert decision).

³⁷¹ See *supra* Section I.B.3.

displacing cigarettes may place an unfair harm on children to benefit adults. FDA may face difficulty issuing new regulations given other pressing matters, including the expedited court-mandated review of e-cigarette products and a large “backlog” of applications from ten years of “enforcement discretion.” Due to the threat of litigation for delays in review, FDA is incentivized to prioritize premarket review of new products over promulgating new regulations, which itself could draw litigation. FDA’s transparency about its resource limitations is essential to securing the agency’s future funding. Even without further funding, the public health importance of reducing tobacco addiction necessitates a pool of personnel and resources at FDA dedicated to limiting nicotine content in tobacco products. Limiting nicotine content strikes at a root cause of tobacco addiction: the addicting constituent itself.

A flavor ban would make e-cigarettes far less attractive to youth. Fruit and mint flavors, which are strongly appealing to kids,³⁷² could be banned, while adults who wish to transition may use unflavored or tobacco-flavored e-cigarettes. The flavor ban may also be paired with a ban on menthol cigarettes—the last remaining cigarette flavor in the United States. Flavors are intrinsically alluring and fun and have little to no place in tobacco products.³⁷³

Taxation is effective at reducing consumption and raising money. A 10% increase in cost is predicted to reduce consumption by 4-5%.³⁷⁴ Given that youth generally do not have a stable income, youth use appears to drop twice as much as adult use after an equivalent change in price.³⁷⁵ E-cigarette taxation, therefore, benefits youth and offers some targeting to the desired population. A federal tax increase would have broader impact, but may draw opposition on federalism grounds. State taxes may be more politically feasible, although some states would continue to opt for minimal taxes. Industry fervently opposes both.

More states should ban all tobacco use (including vaping) in bars, restaurants, parks, and public spaces. So-called smoke-free laws can reduce tobacco use,³⁷⁶ establish anti-tobacco norms, and reduce exposure to bystanders of second-hand aerosol from e-cigarettes.³⁷⁷

³⁷² See Cullen, *supra* note 17, at 2101.

³⁷³ Two exceptions that do not seem attractive to kids: flavored nicotine gum and tobacco-flavored e-cigarettes.

³⁷⁴ NAT’L CANCER INST., *supra* note 355, at 112.

³⁷⁵ See *id.* at 136.

³⁷⁶ See *Smokefree Policies Reduce Smoking*, CTRS. FOR DISEASE CONTROL & PREVENTION, https://www.cdc.gov/tobacco/data_statistics/fact_sheets/secondhand_smoke/protection/reduce_smoking/index.htm (last updated Sept. 11, 2020).

³⁷⁷ See James F. Thrasher, Rosaura Perez-Hernández, Kamala Swayampakala, Edna Arillo-Santillán & Matteo Bottal, *Policy Support, Norms, and Secondhand Smoke Exposure Before and After Implementation of a Comprehensive Smoke-Free Law in Mexico City*, 100 AMERICAN J. PUB. HEALTH 1789, 1789 (2010).

The minimum purchase age of 21 could benefit from further enforcement funding.

Tobacco advertising has become more difficult to track given the individualized nature of social media advertising. Tobacco companies should be required to produce all promotional materials for FDA review and public scrutiny. Companies which target youth should lose the privilege of selling tobacco products, as under the TCA their products could be considered antagonistic to the public health. Social media companies, too, could be enlisted to submit logs of tobacco advertising, noting the age of the person who saw the advertisement.

C. *A New Way of Conceiving and Regulating Addicting Products*

Given multiple waves of addiction in the United States,³⁷⁸ many of which are from legal products, it is time for a new regulatory regime for addicting products. The regime must be established *ex ante*, before we know the identity of the product, because establishing an effective regulatory regime *ex post* in the face of strong market power is difficult. Therefore, a regime must be framed broadly around addicting products. Jurisdiction over new products must be automatic.

Therefore, Congress ought to pass a statute granting FDA, or potentially a new expert agency, jurisdiction over products or substances that cause addiction or dependence, are sold in the legal market, and not otherwise subject to another agency's jurisdiction. Congress should mandate that all such products sold in interstate commerce be subject to several constraints: (1) no marketing without completion of premarket review, without exception, and no deadline for completion of premarket review; (2) mandatory enforcement against unreviewed products offered for sale; (3) approval only for products that would benefit the public health, and would *not* cause a significant health harm, including addiction or diversion; (4) imposition of constraints to ensure that the product continues to be used appropriately; (5) immediate and mandatory market removal for products that begin to show significant signs of addiction of new users, diversion, or association with significant illness or death; (6) mandatory strict liability for youth use, for any association with illness, addiction, or death, or for diversion or illicit use; and (7) mandatory self-insurance to cover sellers' tort liabilities. While this regime appears uniquely robust, so is addiction uniquely noxious and abnormally dangerous, and market participants must be held to the highest standard. Strict liability has precedent in products liability, where manufacturers who sell dangerous or defective products may be held liable regardless of intent.³⁷⁹ Ample funding is required, too, in order that the agency be able to

³⁷⁸ F. Scott Hall & Klaus A. Miczek, *Emerging Threats in Addiction: Will Novel Psychoactive Substances Contribute to Exacerbating the Ongoing Drug Overdose Epidemic?*, 236 PSYCHOPHARMACOLOGY 839, 840 (2019).

³⁷⁹ See John C.P. Goldberg & Benjamin C. Zipursky, *The Easy Case for Products Liability Law: A Response to Professors Polinsky and Shavell*, 123 HARV. L. REV. 1919, 1943–44 (2010).

compete for scientists with regulated industry, surveil infringements, enforce the law, and defend against litigation. The agency must be independent so as to reduce political and corporate influence. Because this regime would apply retroactively, there may have to be exemptions for existing addicting products in broad use, such as caffeine.

CONCLUSION

E-cigarettes are the newest recognized wave of addiction, overlapping with stimulants, opioids, cigarettes, and others.³⁸⁰ Addicting products are frequently sold in legal markets, yet they can cause immense harm all the same. Now, more than 50 years after the Surgeon General's report on the harms of cigarettes, history is repeating itself. What appears to be a robust regulatory regime, enshrined in the Tobacco Control Act and administered by FDA, has had a surprisingly small impact on a rising youth e-cigarette epidemic. FDA has faced barriers at every turn, erected by all three branches of federal government and by regulated industry. Although states and cities retain some authority over tobacco products, much is preempted, and federal e-cigarette regulation has been disappointing.

A new approach to addiction is needed. This approach requires a deep skepticism of addicting products rooted in their history and multifaceted risks to public health. Often, by the time we realize addiction has set in, we are too late. Addicting products require a powerful *ex ante* and *ex post* regulatory system involving actual premarket review, robust standards for marketing, and strict liability for product harms.

³⁸⁰ *E.g.*, Anna Lembke, Jennifer Papac & Keith Humphreys, *Our Other Prescription Drug Problem*, 378 NEW ENG. J. MED 693 (2018) (benzodiazepines).